

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Patent of

ALOIS A. LANGER,
 STEVE A. KOLENIK,
 MARLIN S. HEILMAN,
 MIECZYSLAW MIROWSKI and
 MORTON M. MOWER

Patent No.: 4,407,288
 Issued: October 4, 1983
 Assignee: Mieczyslaw Mirowski

For: IMPLANTABLE HEART STIMULATOR
 AND STIMULATION METHOD

Transmittal Letter For
Application for Patent Term Extension Under 35 USC §156 and 37 CFR §1.740

Commissioner of Patents and Trademarks
 Box Patent Ext.
 Washington, DC 20231

RECEIVED

AUG 16 1994

Dear Sir:

SPECIAL PROGRAMS OFFICE
A/C PATENTS

Enclosed is an original and four photocopies of an application for patent term extension.

The application is informal under 37 CFR §1.740 insofar as written authorization for me to act on behalf of the beneficial owner, the Estate of Mieczyslaw Mirowski (now deceased), assignee of record, has not yet been received from Anna Mirowski, Personal Representative of the Estate of Mieczyslaw Mirowski.

However, the application is complete under 37 CFR §1.741, and thus please grant a filing date to the application.

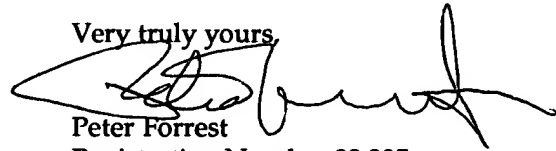
The application is being submitted by Cardiac Pacemakers, Inc., licensee of US Patent 4,407,288 and holder of the regulatory approval granted with respect to the regulatory review period creating the eligibility for extension of the term of US Patent 4,407,288. I am authorized to act on behalf of Cardiac Pacemakers, Inc. in this regard.

To the extent that this situation is contrary to 37 CFR §1.34(a), please grant a limited and temporary suspension of 37 CFR 1.34(a), *sua sponte* and without petition, pending resolution of the matter in response to an order to show cause or by way of petition, as set forth in 37 CFR §1.740(c).

Please charge the \$1,000 fee for the application for patent term extension under 37 CFR §1.20(j), along with any underpayment, or credit any overpayment, to Deposit Account 03-0667.

If you have any questions, please contact me at your convenience.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Peter Forrest', written over the typed name.

Peter Forrest

Registration Number 33,235

Assistant Secretary of Cardiac Pacemakers, Inc.

August 15, 1994

CARDIAC PACEMAKERS, INC.
Mail Stop A390
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA
1-800-CARDIAC, ext. 4400 (voice)
(612) 582-4400 (direct voice)
(612) 582-2926 (facsimile)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Patent of

ALOIS A. LANGER,
STEVE A. KOLENIK,
MARLIN S. HEILMAN,
MIECZYSLAW MIROWSKI and
MORTON M. MOWER

Patent No.: 4,407,288
Issued: October 4, 1983
Assignee: Mieczyslaw Mirowski

For: IMPLANTABLE HEART STIMULATOR
AND STIMULATION METHOD

Application for Patent Term Extension Under 35 USC §156 and 37 CFR §1.740

Commissioner of Patents and Trademarks
Box Patent Ext.
Washington, DC 20231

Dear Sir:

RECEIVED

AUG 16 1994

SPECIAL PROGRAMS OFFICE
A/C PATENTS

Please extend the term of US Patent 4,407,288 under 35 USC §156 by a total of 1107 days. The following information, numbered according to like numbered sub-sections of 37 CFR §1.740(a), supports this request.

(1) The Approved Product

The approved product is the CPI® Ventak® PRx® AICD™ System, an implantable cardioverter defibrillator and ventricular pacing system manufactured by Cardiac Pacemakers, Inc. (CPI). The system primarily comprises an implantable Ventak® PRx® Model 1700 or Model 1705 Pulse Generator, an external Prescriptor® System (programmer) Model 2850, and a Program Disk (programmer software) Model 2860. (The system is designed for use with a variety of cardiac leads along with ancillary accessories such as lead adapters, wrenches, magnets, electrical cables, *etc.*, none of which were subject to the specific regulatory review at issue.) The system detects and terminates ventricular tachycardia and ventricular fibrillation, and provides pacing for bradycardia.

The pulse generators are multimodal treatment systems for patients with serious or potentially serious ventricular arrhythmias. In addition to delivering shocks for terminating malignant arrhythmias, a wide variety of antitachycardia pacing schemes are available to terminate slower, more stable ventricular tachyarrhythmias. Bradycardia pacing is available for bradycardia as well as to support the cardiac rhythm after defibrillation shock therapy.

Programmable parameter settings allow incremental adjustment of therapy to meet patient needs.

The Model 1700 and 1705 Pulse Generators differ slightly in volume and weight due primarily to different connection ports for the electrode leads. Specifically, the Model 1700 Pulse Generator has two 3.2mm morphology/defibrillation lead ports and one 3.2mm inline bipolar rate-sensing/pacing lead port. The Model 1705 Pulse Generator has two 6.1mm morphology/defibrillation lead ports and two 4.75mm rate-sensing/pacing lead ports. These differences are not relevant to the reading of the claims of US Patent 4,407,288 on either model of pulse generator, and thus both models are considered to be one product for purposes of regulatory review under the FFDCA as well as the scope and term of US Patent 4,407,288.

The Prescriptor[®] System Model 2850 programmer system, when loaded with software from the Program Disk Model 2860, communicates with the Ventak[®] PRx[®] Model 1700 and Model 1705 Pulse Generators to: program therapy parameters for the implanted pulse generator; interrogate the programmed pulse generator; monitor and analyze patient data, and evaluate alternative prescription modes; store patient data that can be recalled later for analysis; generate printed reports that detail pulse generator functions, stored patient data, and test results; and perform noninvasive diagnostic tests in an electrophysiology laboratory, operating room, emergency room, or at a patient's bedside.

(2) The Federal Statute under which Regulatory Review Occurred

The US Food and Drug Administration (FDA) reviewed the CPI[®] Ventak[®] AICD[™] System under Section 515 of the Federal Food, Drug and Cosmetic Act (FFDCA).

(3) The Date on which the Product Received Permission for Commercial Marketing

The FDA approved the CPI[®] Ventak[®] AICD[™] System under Section 515 of the FFDCA on June 17, 1994.

(4) The Active Ingredient of a Drug Product

Not applicable.

(5) Timely Filing of this Application

This application is being submitted within the sixty day period set forth in 37 CFR §1.720(f). The product was approved for commercial marketing on Friday, June 17, 1994, the 168th day of

1994. The last date on which this application could be filed is Tuesday, August 16, 1994, the 228th (168+60) day of 1994.

(6) The Patent

US Patent 4,407,288 issued October 4, 1983 in the names of Alois A. Langer, Steve A. Kolenik, Marlin S. Heilman, Mieczyslaw Mirowski, and Morton M. Mower. The expiration date of the patent is October 4, 2000.

(7) Copy of the Patent

A full copy of US Patent 4,407,288 is enclosed.

(8) Disclaimers/Corrections/Maintenance Fee Receipts

No disclaimer of the patent has been filed. No certificate of correction to the patent has been filed. Copies of the Maintenance Fee Receipts for each of the two maintenance fees which have been paid to date are enclosed. No reexamination certificate has been issued for the patent.

(9) The Approved Product and the Patent

US Patent 4,407,288 claims the Ventak® PRx® AICD™ System, and the method of using the system, in at least the claims specifically identified below.

Claim 1 The Ventak® PRx® AICD™ System employs an implantable pulse generator to provide electrical stimulation to the heart. The pulse generator can detect the presence of multiple arrhythmias, and may be programmed to treat any single arrhythmia or multiple arrhythmias. The system determines cardiac condition and selects a unique mode of operation corresponding to the arrhythmia (and preprogrammed command parameters specific to the arrhythmia). The system then administers the appropriate therapy for the condition detected.

Claim 2 The Ventak® PRx® AICD™ System detects bradycardia, ventricular tachyarrhythmia, and ventricular fibrillation. It provides pacing for bradycardia, anti-tachycardia pacing, and shock therapy for cardioversion or defibrillation. The Ventak® PRx® AICD™ system operates continuously to monitor and treat those conditions.

Claim 3 The Ventak® PRx® AICD™ System provides cardiac pacing for bradycardia

or post-shock bradycardia as one mode of operation.

- Claim 4** The Ventak® PRx® AICD™ System provides cardiac shocks for cardioversion of ventricular tachycardia as one mode of operation.
- Claim 5** The Ventak® PRx® AICD™ System provides cardiac shocks for ventricular defibrillation as one mode of operation.
- Claim 7** The Ventak® PRx® Model 1700 and Model 1705 Pulse Generators are microprocessor-controlled systems, programmed externally from the Prescriptor® Model 2850 System (using the Program Disk Model 2860) with respect to a variety of bradycardia, cardioversion, and defibrillation parameters.
- Claim 10** See claim 1 above.
- Claim 11** See claim 2 above.
- Claim 12** See claim 3 above.
- Claim 13** See claim 4 above.
- Claim 14** See claim 5 above.
- Claim 18** The Ventak® PRx® Model 1700 and Model 1705 Pulse Generators employ programmable memory registers to store definitional and operating parameters corresponding to the multiple modes of operation. Data is transferred into and out of the registers under the microprocessor direction by means of an input/output data channel. The data values are used by the system to deliver therapy specifically tailored to the arrhythmic condition of the patient.
- Claim 19** See claim 18 above. Also, the Ventak® PRx® System provides for increasing cardioversion/defibrillation energy levels as described for claim 31, below.
- Claim 20** See claims 1 and 10 above.
- Claim 22** The Ventak® PRx® Model 1700 and Model 1705 Pulse Generators have data input/output capability for exchanging data with the Prescriptor® System Model 2850.

- Claim 23** See claims 1 and 18 above.
- Claim 24** See claim 3 above.
- Claim 25** See claim 4 above.
- Claim 26** See claim 5 above.
- Claim 29** See claims 1 and 22 above.
- Claim 30** Pacing pulse amplitude is programmable at 2.5, 5.0, or 7.5 volt (nominal=7.5V); first and second shock cardioversion/defibrillation energy is programmable at 0.10, 0.25, 0.50, and 0.75 joule, 1-10 joule in 1 joule increments, 10-20 joule in 2 joule increments, 25, 30, or 34 joule (nominal=34J).
- Claim 31** In a given episode of cardioversion/defibrillation therapy, up to five shocks may be delivered by the system. The first and second shock energies are programmable as described in claim 30, above; the third, fourth, and fifth energies are fixed at 34 joules. Thus, the system can be programmed to provide a sequence of successive shocks of increasing energy level until defibrillation is completed.
- Claim 32** The system may be preprogrammed to provide 0 or 5 (nominal=5) defibrillating pulses in each episode of antitachycardia therapy.
- Claim 33** See claim 32 above.
- Claim 36** See claims 1 and 22 above.
- Claim 37** See claims 1 and 18 above.

(10) Relevant Dates and Other Information

The holder of the regulatory approval for the CPI® Ventak® AICD™ System is Cardiac Pacemakers, Inc. (CPI), a wholly-owned subsidiary of Eli Lilly and Company, exclusive licensee of US Patent 4,407,288.

Under 37 CFR §1.740(a)(10)(v), the following events and dates are applicable to the regulatory review and approval sought and granted to CPI for the Ventak® AICD™ System. (37 CFR §1.740(a)(10)(i-iv) are not applicable.)

Effective Date of Investigational Device Exemption (IDE): November 21, 1990
(Please note that this is the date that the IDE was conditionally accepted.)

IDE Number: G900150

Date of Pre-Market Approval Application (PMAA): December 20, 1991

Number of PMAA: P910077

Date of Approval of PMAA: June 17, 1994

(11) Significant Activities

A partial listing of key events and mailing dates of correspondence between Cardiac Pacemakers, Inc. and the Food and Drug Administration (FDA) during the regulatory review period appears below. The number and frequency of events clearly establishes that, during the entire regulatory review period, Cardiac Pacemakers, Inc. continuously and diligently pursued approval by the FDA under the FFDCA to commercially distribute the CPI® Ventak® PRx® AICD™ System.

Investigational Device Exemption (IDE) Phase

Application	July 25, 1990
Disapproval	August 24, 1990
First Amendment	September 11, 1990
Disapproval of Amended IDE	October 11, 1990
Second Amendment	October 22, 1990
Conditional Approval	November 21, 1990
Submission of Additional Information	November 29, 1990
Supplement	December 18, 1990
Submission of Additional Information	December 18, 1990
Supplement	December 18, 1990
Supplement	January 17, 1991
Continued Conditional Approval	January 18, 1991
Approval of Supplement	January 18, 1991
Conditional Approval of Supplement	February 21, 1991
Supplement	March 5, 1991
Amendment	March 5, 1991
Supplement	March 8, 1991
Approval of Supplement	March 28, 1991
Approval of IDE Application	March 28, 1991
Approval of Supplement	April 10, 1991
Supplement	April 23, 1991
Approval of Supplement	May 2, 1991
Supplement	July 29, 1991
Supplement	August 2, 1991
Approval of Supplement	August 12, 1991

Investigational Device Exemption (IDE) Phase, continued

Approval of Supplement	August 20, 1991
Supplement	September 6, 1991
Supplement	September 16, 1991
Questions Regarding Pre-Market Approval Application	September 30, 1991
Supplement	October 8, 1991
Approval of Supplement	October 9, 1991
Approval of Supplement	October 16, 1991
Response to Questions	October 25, 1991
Approval of Supplement	November 4, 1991
Submission of Data	November 11, 1991
Confirmation of Meeting to Review Data	November 13, 1991
Approval of Supplement	January 2, 1992
Approval of Supplement	January 2, 1992
Supplement	January 10, 1992
Approval of Supplement	February 12, 1992
Approval of Supplement	February 14, 1992
Supplement	March 27, 1992
Approval of Supplement	April 30, 1992
Approval of Supplement	April 30, 1992
Supplement	May 1, 1992
Supplement	May 12, 1992
Supplement	May 13, 1992
Conditional Approval of Supplement	June 3, 1992
Approval of Supplement	June 3, 1992
Disapproval of Supplement	June 11, 1992
Correction of Disapproval of Supplement	June 19, 1992
Request for Modification	July 7, 1992
Supplement	July 20, 1992
Approval of Supplement	August 11, 1992
Confirmation of Telephone Conversation	August 20, 1992
Supplement	August 21, 1992
Confirmation of Telephone Conversation	September 1, 1992
Supplement	September 8, 1992
Supplement	September 17, 1992
Conditional Approval of Two Supplements	September 24, 1992

Investigational Device Exemption (IDE) Phase, continued

Disapproval of Supplement	October 13, 1992
Supplement	October 16, 1992
Conditional Approval of Supplement	November 19, 1992
Supplement	December 23, 1992
Supplement	January 7, 1993
Response to Conditional Approval of Supplement	January 7, 1993
Conditional Approval of Supplement	January 22, 1993
Approval of Supplement	January 29, 1993
Approval of Supplement	January 29, 1993
Supplement	February 9, 1993
Supplement	February 8, 1993
Response to Conditional Approval of Supplement	March 4, 1993
Approval of Supplement	March 11, 1993
Approval of Supplement	March 19, 1993
Supplement	March 31, 1993
Approval of Supplement	April 2, 1993
Supplement	April 13, 1993
Confirmation of Telephone Conversations	April 29, 1993
Conditional Approval of Supplement	April 30, 1993
Supplement	May 3, 1993
Disapproval of Supplement	May 12, 1993
Supplement	May 14, 1993
Response to Questions	June 1, 1993
Approval of Supplement	June 3, 1993
Supplement	June 11, 1993
Approval of Two Supplements	June 17, 1993
Supplement	June 28, 1993
Approval of Supplement	June 30, 1993
Approval of Supplement	July 14, 1993
Supplement	July 15, 1993
Approval of Supplement	July 29, 1993
Conditional Approval of Supplement	August 13, 1993
Supplement	September 13, 1993
Supplement	October 8, 1993
Approval of Supplement	October 14, 1993

Investigational Device Exemption (IDE) Phase, continued

Supplement	October 26, 1993
Conditional Approval of Supplement	November 26, 1993
Supplement	December 6, 1993
Approval of Supplement	January 6, 1994
Supplement	February 22, 1994

Pre-Market Approval Application (PMAA) Phase

Application	December 20, 1991
Threshold Determination	February 14, 1992
Notice of Deficiencies	March 5, 1992
Notice of Deficiencies	May 5, 1992
Amendment	August 1, 1992
Amendment	August 5, 1992
Amendment	October 7, 1992
Amendment	February 11, 1993
Amendment	February 25, 1993
Amendment	March 8, 1993
Notice of Deficiencies	June 7, 1993
Amendment	June 25, 1993
Response to Questions	June 29, 1993
Amendment	July 7, 1993
Notice of Panel Meeting	July 7, 1993
Amendment	July 12, 1993
Amendment	August 19, 1993
Notice of Deficiencies	October 25, 1993
Amendment	November 11, 1993
Amendment	December 6, 1993
Amendment	December 7, 1993
Submission of Additional Copies of November 11, 1993 Amendment	March 10, 1994
Notice of Approvable PMAA	April 29, 1994
Amendment	May 6, 1994
Amendment	June 10, 1994
Submission of Summary of Safety and Effectiveness	June 16, 1994
Approval of PMAA	June 17, 1994
Submission of Amended Labeling	June 20, 1994

(12) Eligibility for and Calculation of Extension

In the opinion of the Estate of Mieczyslaw Mirowski, US Patent 4,407,288 is eligible for an extension of patent term under 35 USC §156 in the amount of 1107 days, as set forth below.

(a) Eligibility for extension under 35 USC §156

- (1)** This application is being submitted prior to the expiration of US Patent 4,407,288 on October 4, 2000.
- (2)** US Patent 4,407,288 has never had an extension of patent term.
- (3)** This application is being submitted on behalf of the Estate of Mieczyslaw Mirowski, now deceased, the assignee of record. Proof of authority to submit this application, in accordance with 35 USC §156(d) and 37 CFR §1.740(b)(1), will be provided in response to an order to show cause why the USPTO should not deny this application under 35 USC §156(c)(3) and 37 CFR §1.730; or by way of petition under 37 CFR §1.181, §1.182, or §1.183, all as provided by 37 CFR §1.740(c).
- (4)** The product was subject to regulatory review by the US Food and Drug Administration (FDA) under Section 515 of the Federal Food, Drug and Cosmetic Act (FFDCA).
- (5)** The permission for commercial marketing under Section 515 of the FFDCA was the first permission for commercial marketing for the product.

(b) Calculation of Length of Extension

The period beginning on the date a clinical investigation on humans involving the product was begun, *i.e.*, the date the Application for Investigational Device Exemption (IDE) was conditionally accepted (November 21, 1990), and ending on the date the Pre-Market Approval Application (PMAA) was filed (December 20, 1991), is 394 days.

The period beginning on the date the PMAA was filed (December 20, 1991), and ending on the date the product was approved for commercial marketing (June 17, 1994), is 910 days (taking the leap day of February 29, 1992 into account).

The sum of the two periods above is 1304 days. US Patent 4,407,288 issued on October 4,

1983, before the September 24, 1984 date of enactment, as defined in 35 USC §(f)(7), of the statute now codified at 35 USC §156. None of the events described in 35 USC §156(g)(6)(B) (i-iii) occurred. Thus, no reduction under 35 USC 156(g)(3)(B) applies, and the total regulatory review period is 1304 days.

US Patent 4,407,288 issued on October 4, 1983, before clinical investigation on humans involving the product began on December 20, 1991, and thus the regulatory review period is not reduced under 35 USC §156(c).

Cardiac Pacemakers, Inc. continuously and diligently worked to secure acceptance of the PMAA by the FDA during the entire period of regulatory review. Therefore, no reduction for lack of diligence should be made under 35 USC §156 (c)(1) or 37 CFR §1.777(d)(1)(ii).

One-half of the period beginning on the date the IDE was conditionally accepted (November 21, 1990), and ending on the date the PMAA was filed (December 20, 1991), is one-half of 394 days, or 197 days. Under 35 USC §156 (c)(2), this amount is subtracted from the length of the regulatory review period. The difference is 1304 days minus 197 days, or 1107 days.

As of the date of commercial approval of the product, June 17, 1994, the patent term remaining (to October 4, 2000) was 2301 days (6.3 years). The sum of this amount and the reduced regulatory period of 1107 days (3.0 years), is 9.3 years, less than the maximum 14 year (5110 days) extended term permitted by 35 USC §156(c)(3) and 37 CFR §1.777(d)(2-4). Thus, the reduced regulatory period is not reduced further to provide a maximum extended term of not greater than 14 years.

US Patent 4,407,288 issued before, but clinical evaluation of the product began after, September 24, 1984. Because commercial marketing of the product also was approved after that date, the maximum amount of extension available is 5 years. The reduced regulatory period of 3.0 years does not exceed this amount. Thus, the limitation of 35 USC §156(g)(4)(B) and 37 CFR §1.777(d)(6) does not apply.

Therefore, US Patent 4,407,288 is eligible for an extension of term of 1107 days. The new expiration date of the patent should be October 16, 2003.

(13) Duty of Disclosure

I acknowledge my duty to disclose to the Commissioner of Patents and Trademarks and the

Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension of patent term of US Patent 4,407,288. I specifically acknowledge the requirements of 37 CFR §1.765.

In this regard, please note two particular issues:

- (1) Extensions of patent term have been previously granted for patents which may also read on the CPI® Ventak® PRx® AICD™ System; and US Patent 4,407,288 may also read on other products which have undergone regulatory review such that other patents on such other products were granted extensions of term.

Specifically, patent term extensions have been granted previously for:

- US Patent B1 Re. 27,757 (a reissue of US Patent 3,614,955, as reflected by Reexamination Certificate Number 638 issued March 10, 1987), based upon regulatory review of implantable defibrillators known as the AID® Model B and AID® Model BR; this patent (now expired) is believed to read on the CPI® Ventak® PRx® AICD™ System. US Patent 4,407,288 is not believed to read on the AID® Model B or Model BR.
- US Patent 4,316,472, based upon regulatory review of an implantable cardioverter defibrillator known as Ventak® P Model 1600, certain claims of which patent also read on certain implantable cardioverter/defibrillators which did not require regulatory review as defined by 35 USC §156(g), specifically those known as Ventak® Model 1550 and Ventak® Model 1555; this patent is believed to read on the Ventak® PRx® Models 1700 and 1705. Certain claims of US Patent 4,407,288 may read on the Ventak® P Model 1600, the Ventak® Model 1550, and the Ventak® Model 1555, depending upon factual issues regarding interpretation of the claims.
- US Patent 4,868,908, based on regulatory review of an implantable cardioverter defibrillator pacer known as Ventritex® Cadence® Tiered Therapy Defibrillator System Model V-100; it is not known if this patent reads on the CPI® Ventak® PRx® AICD™ System. US Patent 4,407,288 is believed to read on the Ventritex® Cadence® Tiered

Therapy Defibrillator System Model V-100.

- US Patent 4,052,991, based upon an implantable cardioverter defibrillator pacer known as Medtronic® PCD® Tachyarrhythmia Control Device Model 7217B; this patent is believed to read on the CPI® Ventak® PRx® AICD™ System. US Patent 4,407,288 is believed to read on the Medtronic® PCD® Tachyarrhythmia Control Device Model 7217B.
- (2) Mr. Gerald Dost of the USPTO and I discussed the eligibility of US 4,407,288 for patent term extension on July 6, 1994. The specific context discussed was the second bullet item above, *i.e.*, that some of the claims of US 4,407,288 may read on at least the CPI® Ventak® P Model 1600, and some of the claims of US 4,316,472 read on the CPI® Ventak® PRx® AICD™ System.

On these facts, 37 CFR §1.720(e)(1) appears to prohibit extension of the term of US Patent 4,407,288 if the "commercial marketing or use" identified in the regulation is read to mean the commercial marketing or use of *any product* which had undergone regulatory review forming the basis for *any* extension, even if such extension was not for US Patent 4,407,288. However, Mr. Dost indicated that 37 CFR §1.720(e)(1) did not prohibit approval of this application, based on the facts as presented in the telephone conversations. I understand that Mr. Dost's interpretation of 37 CFR §1.720(e)(1) was informal and does not substitute for formal review of this application.

(14) Fee

As noted in the letter of transmittal, please charge the \$1,000 fee under 37 CFR §1.20(j) to Deposit Account 03-0667. Please also charge any other fee necessary to process this application to Deposit Account 03-0667.

(15) Notice

Please address all inquiries and correspondence regarding this application to:

Peter Forrest
Mail Stop A390
Cardiac Pacemakers, Inc.
4100 Hamline Avenue North
St. Paul, MN 55112-5798

Please address all telephone calls to Peter Forrest at (612) 582-4400.

(16) Duplicate Papers

Please find enclosed one original and four complete duplicates of this application and all exhibits. One duplicate is required by 37 CFR §1.740(a)(16), and three additional duplicates provided for the convenience of the USPTO at the request of Mr. Dost. I certify as a registered practitioner that all duplicates are true and accurate photocopies of the original.

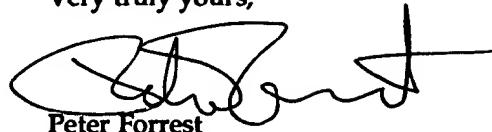
(17) Declaration

I am an attorney authorized to practice before the United States Patent and Trademark Office. I have reviewed and I understand the contents of this application. I believe that US Patent 4,407,288 is subject to extension pursuant to 37 CFR §1.710. I believe that an extension of 1107 days is justified under 35 USC §156 and applicable regulations. I believe that US patent 4,407,288 meets the conditions for extension of term as set forth in 37 CFR §1.720.

All statements in this application made of my own knowledge are true, and all statements in this application made on information and belief I believe to be true. I make these statements knowing that willful false statements and the like may be punished by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may also jeopardize this application for extension of the patent term of US Patent 4,407,288.

If you have any questions, please contact me at your convenience.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Peter Forrest', with a large, stylized initial 'P' and a long horizontal stroke extending to the right.

Peter Forrest

Registration Number 33,235

August 15, 1994

CARDIAC PACEMAKERS, INC.
Mail Stop A390
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA
1-800-CARDIAC, ext. 4400 (voice)
(612) 582-4400 (direct voice)
(612) 582-2926 (facsimile)

[54] **IMPLANTABLE HEART STIMULATOR AND STIMULATION METHOD**

[75] Inventors: Alois A. Langer, Pittsburgh; Steve A. Kolenik, Leechburg; Marlin S. Heilman, Gibsonia, all of Pa.; Mieczyslaw Mirowski, 2405 Velvet Valley Way, Owings Mills, Md. 21117; Morton M. Mower, Lutherville, Md.

[73] Assignee: Mieczyslaw Mirowski, Owings Mills, Md.

[21] Appl. No.: 243,801

[22] Filed: Mar. 16, 1981

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 215,275, Dec. 11, 1980.

[51] Int. Cl.³ A61D 1/36

[52] U.S. Cl. 128/419 PG; 128/419 D

[58] Field of Search 128/419 D, 419 PG

[56] **References Cited****U.S. PATENT DOCUMENTS**

3,805,795	4/1974	Denniston et al.	128/419 D
3,857,398	12/1974	Rubin	128/419 D
3,952,750	4/1976	Mirowski et al.	128/419 D
4,055,189	10/1977	Auerbach et al.	128/419 PG
4,114,628	9/1978	Rizk	128/419 D

FOREIGN PATENT DOCUMENTS

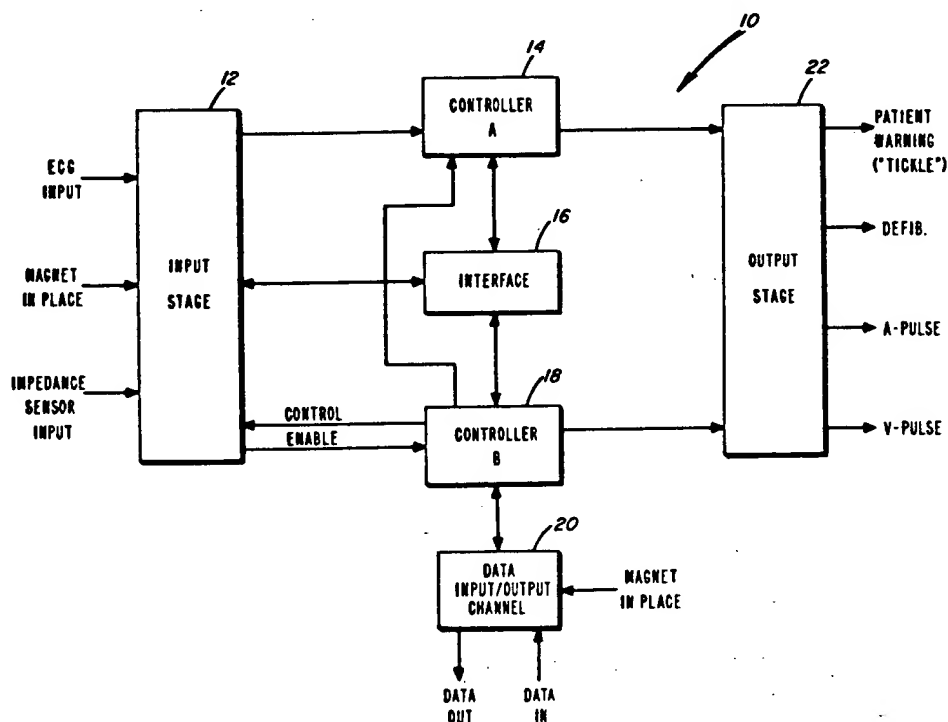
4243 9/1979 European Pat. Off. 128/419 PG

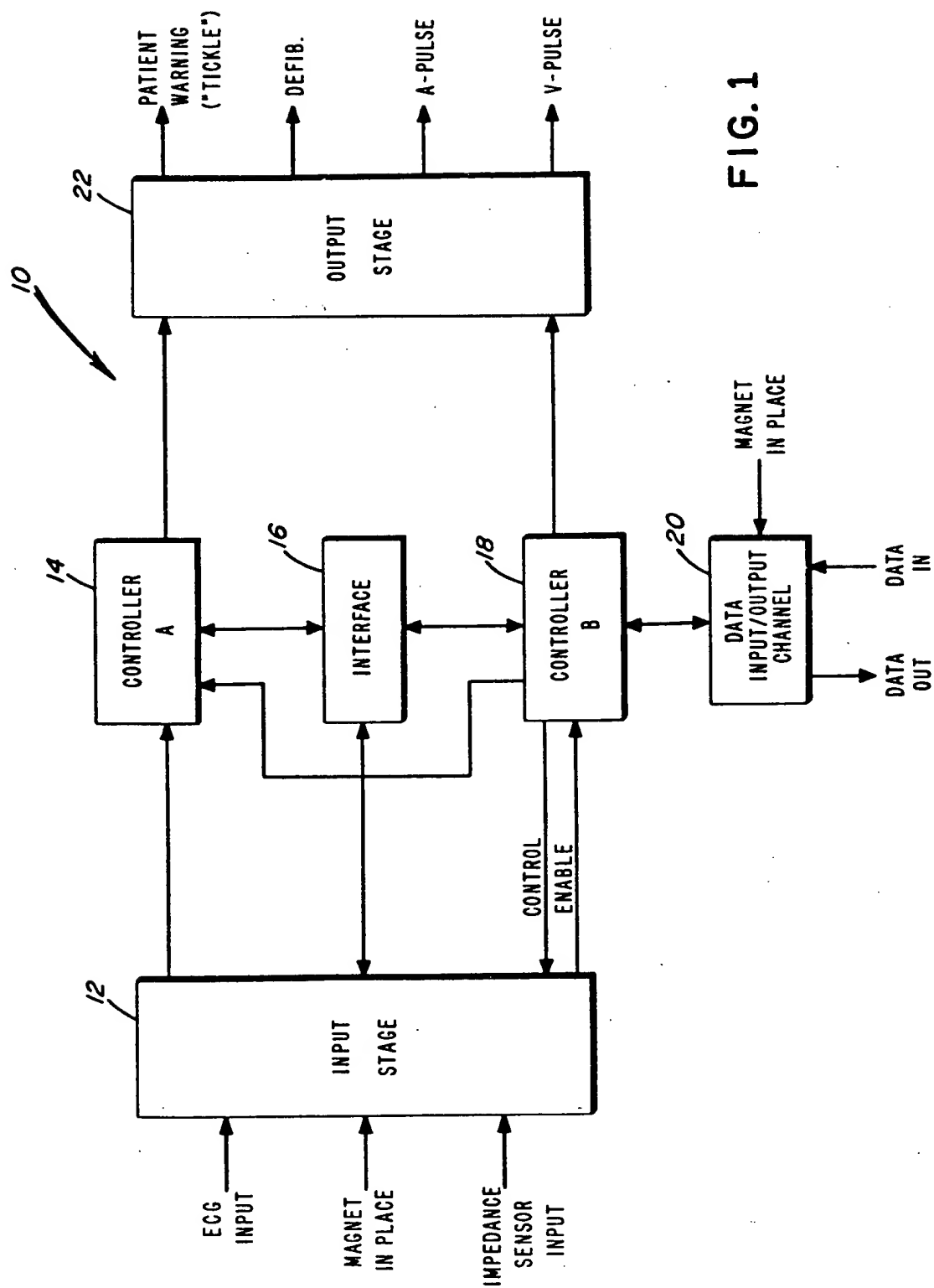
Primary Examiner—William E. Kamm
Attorney, Agent, or Firm—Fleit, Jacobson, Cohn & Price

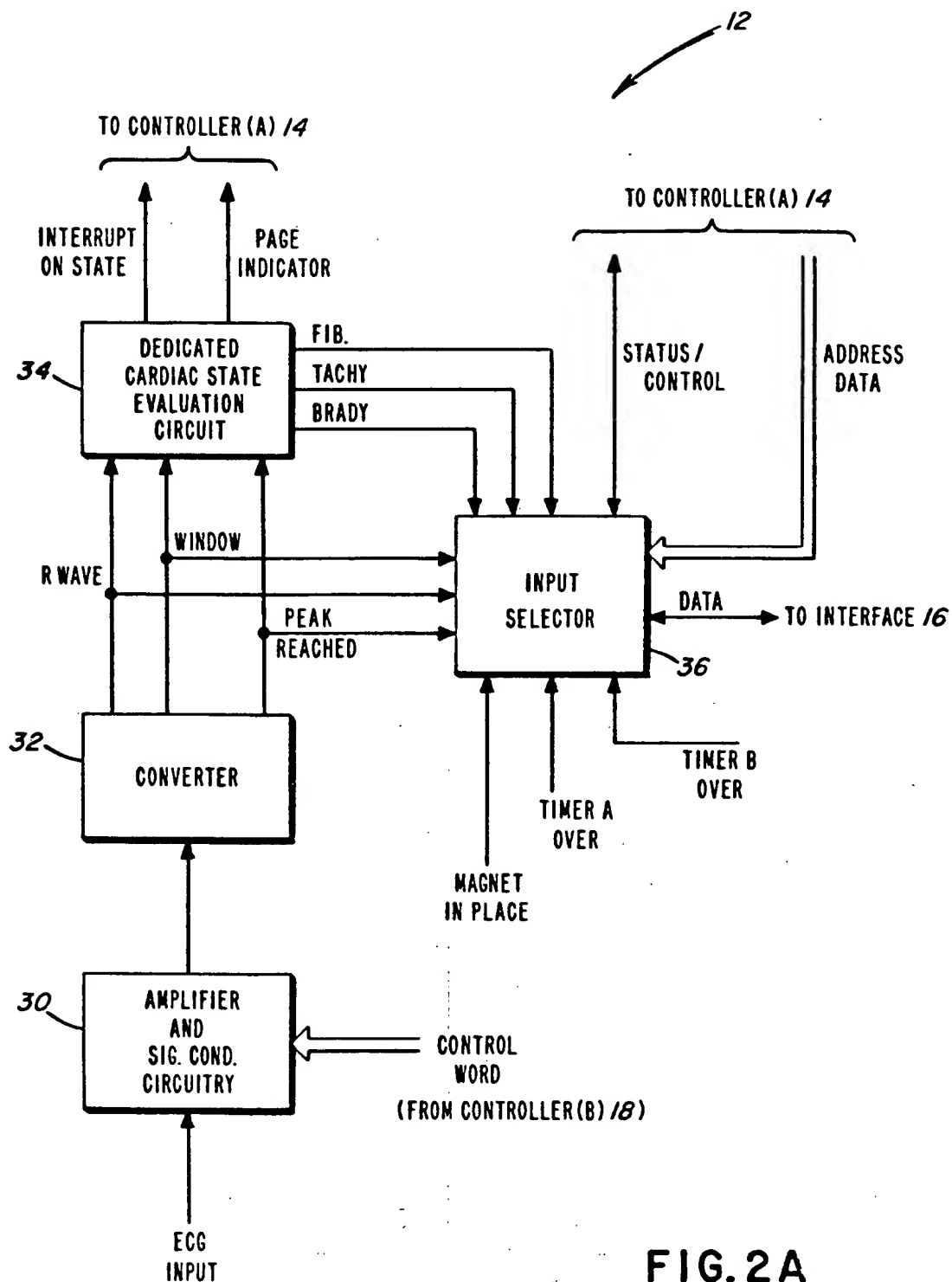
[57] **ABSTRACT**

An implantable heart stimulator and related method calls for the determination of a given heart condition from among a plurality of conditions, the selection of at least one mode of operation for treating the determined condition, and the execution of the mode of operation selected, so as to treat the determined condition. In one embodiment of the invention, wherein a plurality of modes of operation for treating the various conditions are provided, the implantable heart stimulator includes processors, each processor being designed to efficiently execute a respective group of modes of operation. A further embodiment of the present invention calls for the implantable heart stimulator to be implemented by at least one programmable microprocessor. A still further embodiment calls for the provision of a data input/output channel, by means of which data can be provided to and retrieved from the implantable heart stimulator. Operations carried out by the implantable heart stimulator includes cardiac pacing, cardioversion, and automatic defibrillation. In a further embodiment of the implantable heart stimulator and related method, sensing circuitry is provided to determine the presence or absence of an R-wave of the heart, the absence of which causes a pacing operation to be implemented, further sensing circuitry being provided to determine the presence or absence of a forced R-wave of the heart, the absence of a forced R-wave causing ventricular defibrillation to be implemented.

37 Claims, 9 Drawing Figures







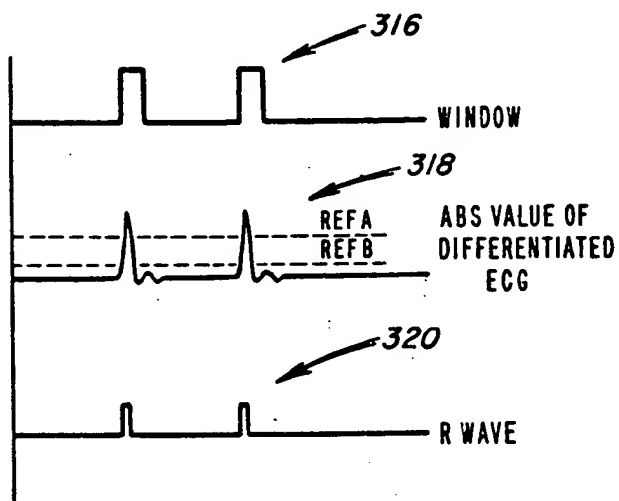
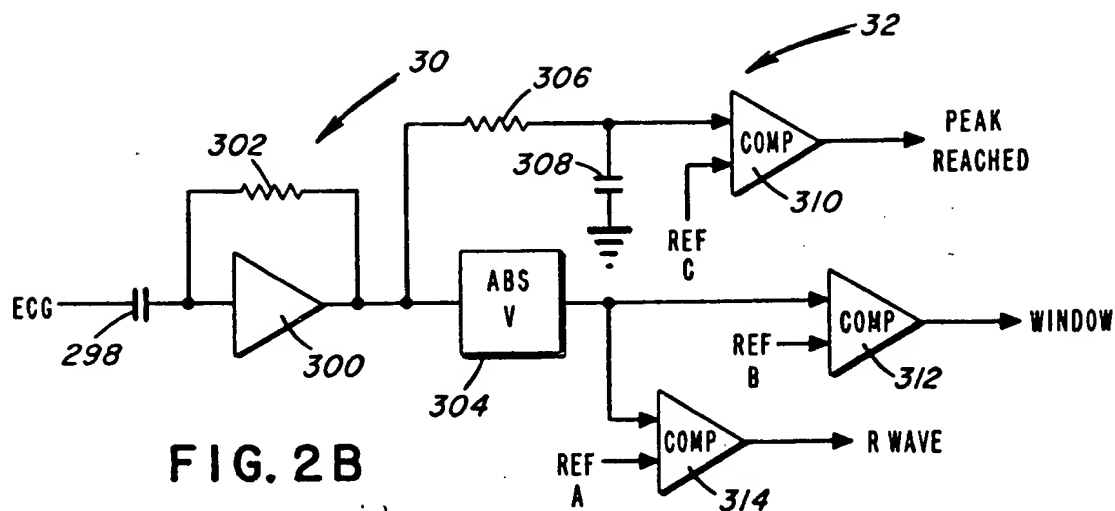
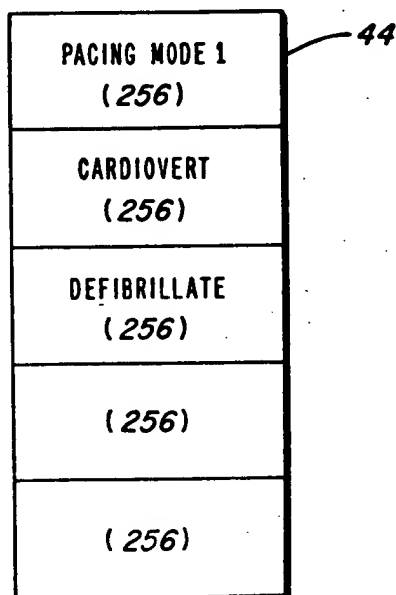


FIG. 3B



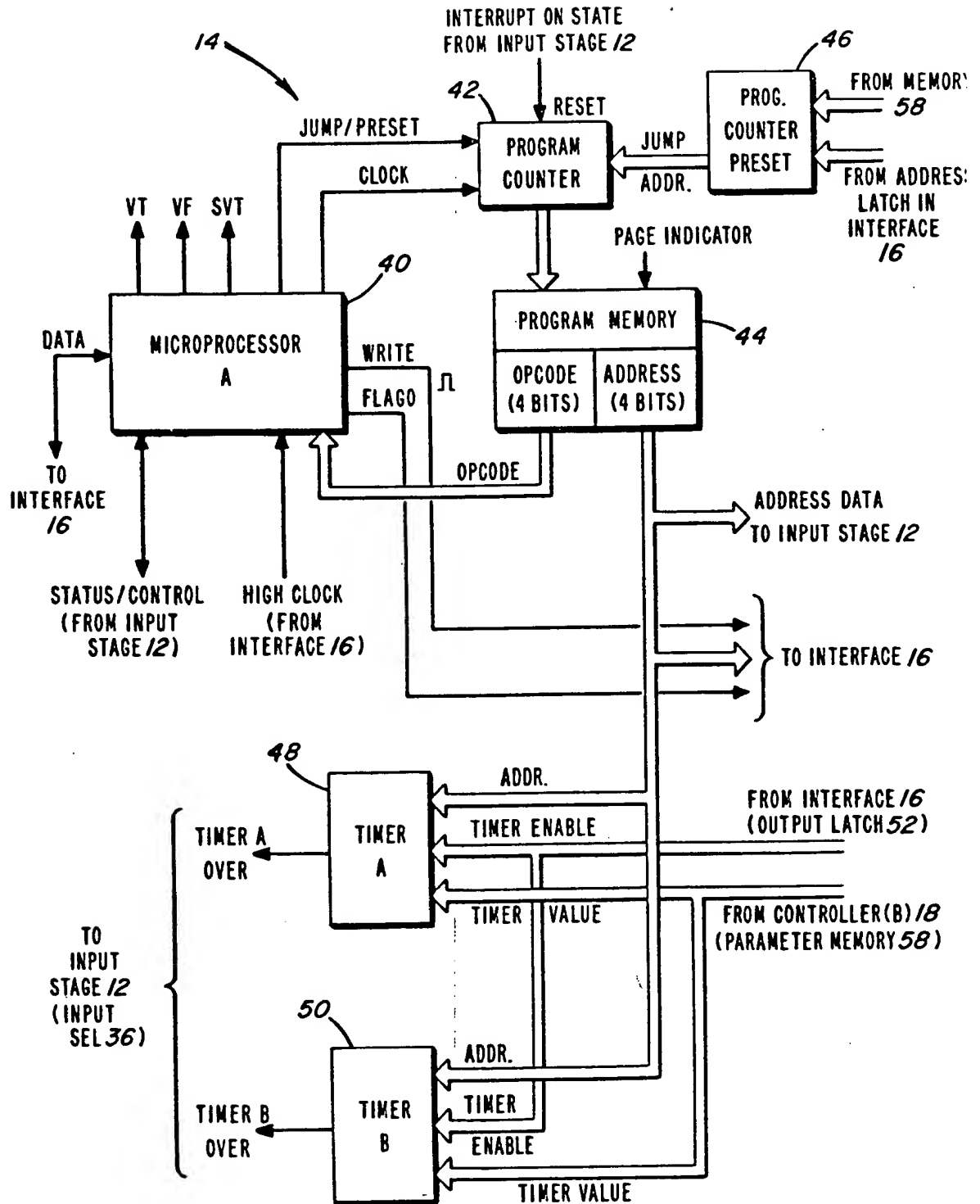
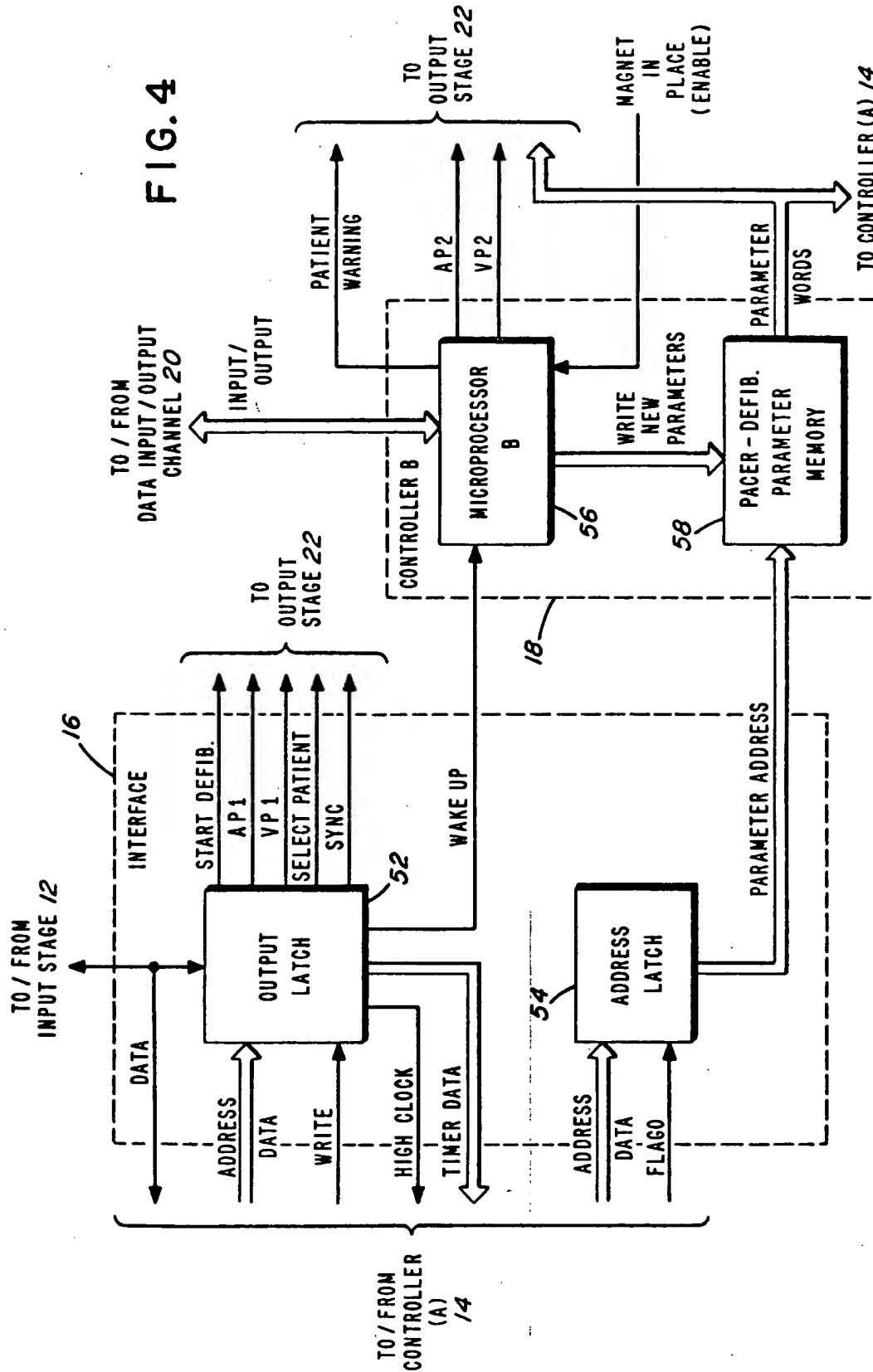


FIG. 3A



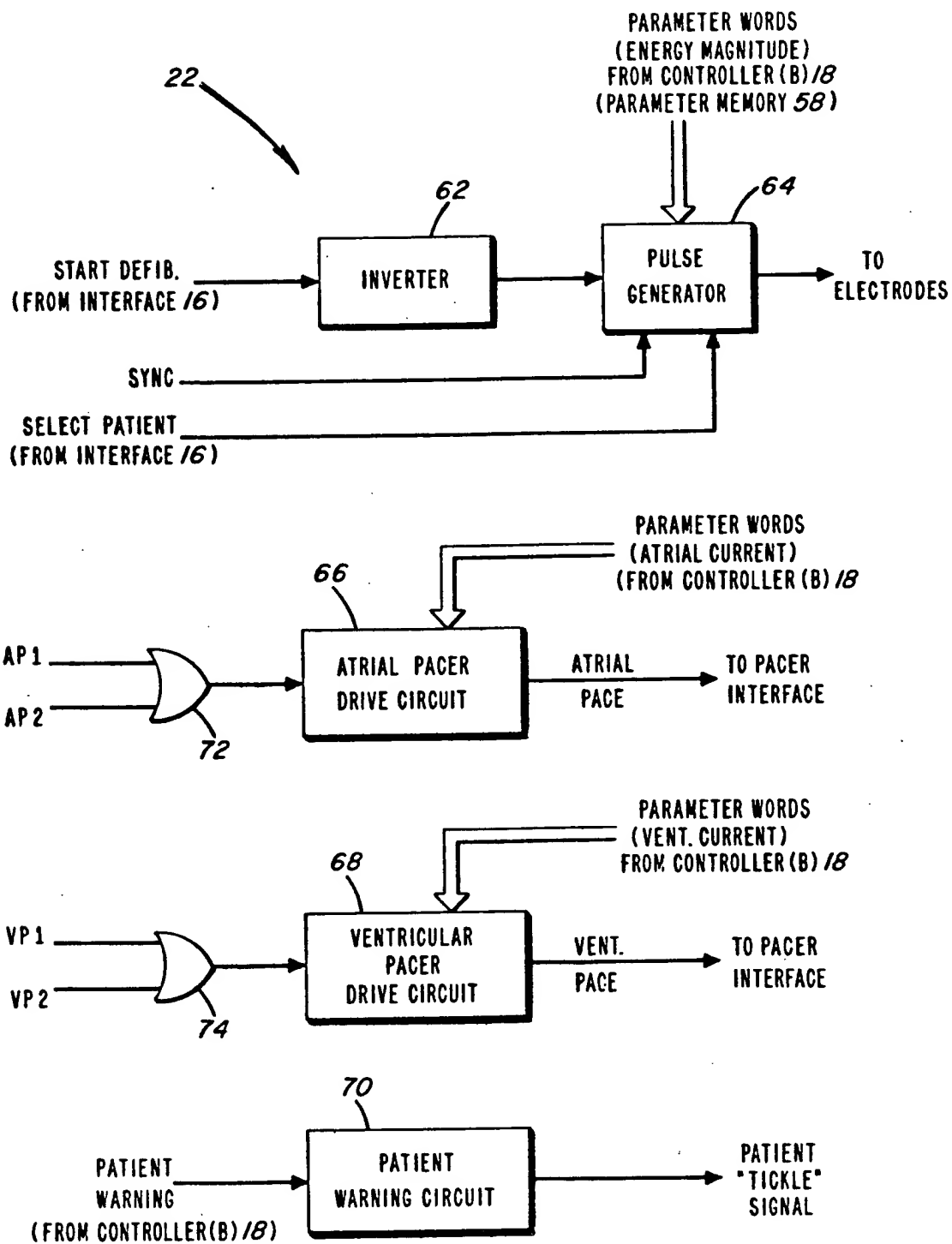


FIG. 5

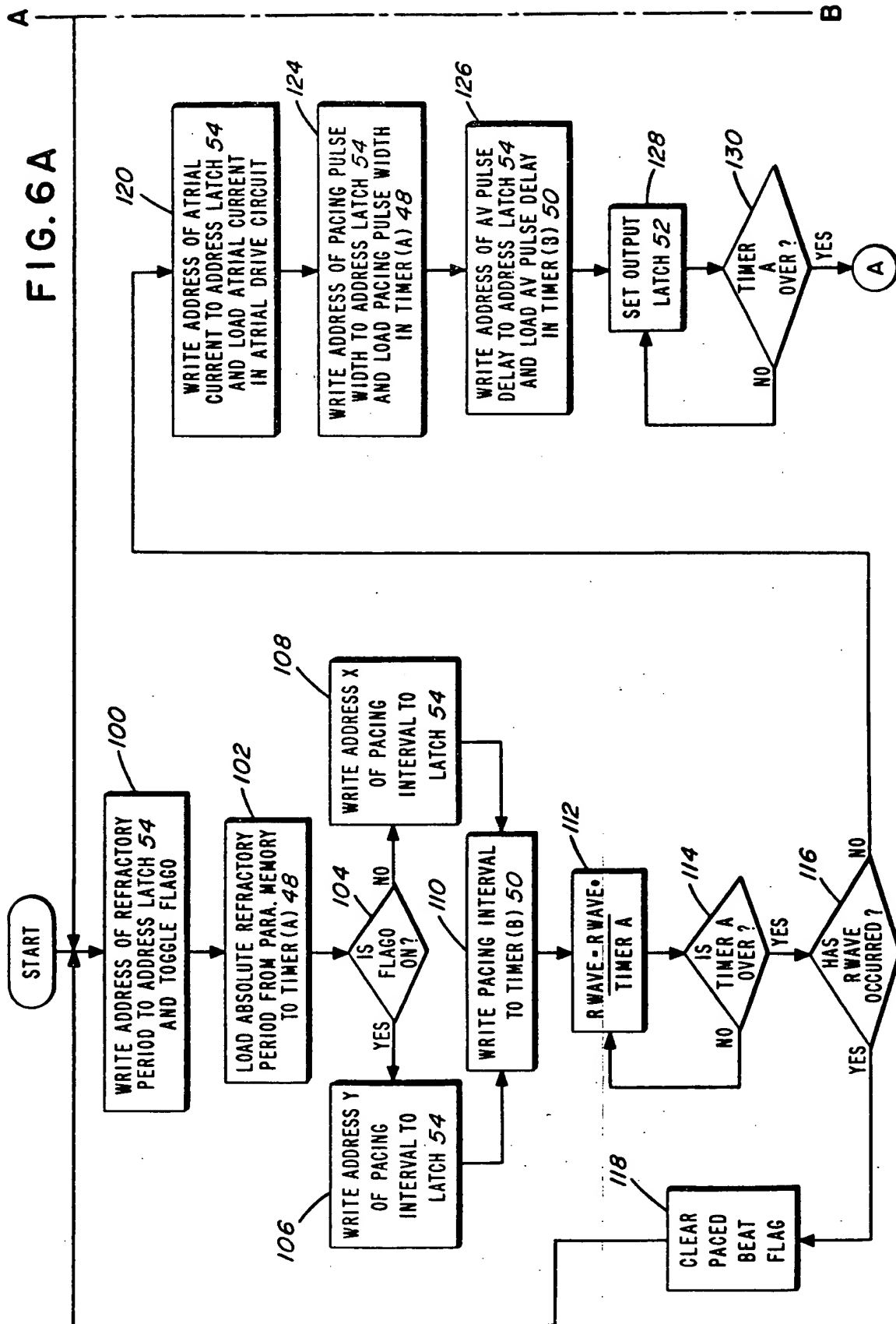
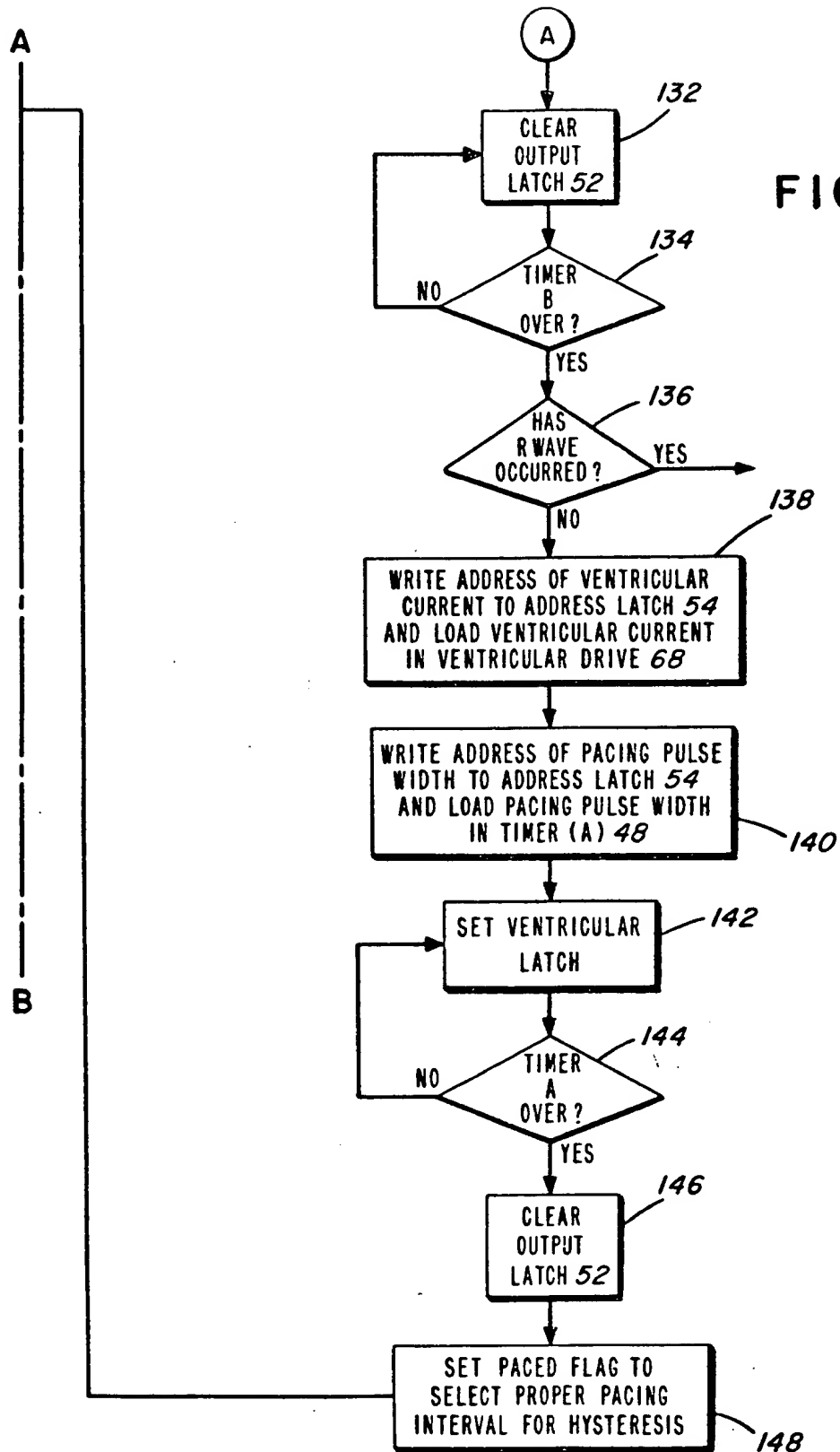


FIG. 6B



IMPLANTABLE HEART STIMULATOR AND STIMULATION METHOD

REFERENCE TO RELATED APPLICATION

This invention is a continuation-in-part of U.S. patent application Ser. No. 215,275 deposited Dec. 11, 1980, and entitled "Implantable Heart Stimulator and Stimulation Method".

FIELD OF THE INVENTION

The present invention relates to an implantable heart stimulator and related method, and more particularly to a highly versatile, externally programmable and implantable heart stimulator capable of functioning in various modes of operation to perform a variety of therapeutic routines in response to recognizable heart disorders or arrhythmias.

BACKGROUND OF THE INVENTION

In recent years, substantial progress has been made in the development of techniques for providing effective medical response to various heart disorders or arrhythmias. The types of contemplated disorders or arrhythmias have typically been treated in the past by drug therapy, or by devices such as pacers, defibrillators, cardioverters, etc.

More recent efforts have resulted in the development of electronic standby defibrillators, such as disclosed in U.S. Pat. No. Re. 27,652 of Mirowski et al (based on original U.S. Pat. No. 3,614,954) and U.S. Pat. No. Re. 27,757 of Mirowski et al (based on original U.S. Pat. No. 3,614,955).

Most recently, efforts have been directed toward the development of miniaturized defibrillating, cardioverting and pacing devices amenable to implantation in the body of a patient subject to heart disorder or arrhythmia. An example of one such implantable device is contained in U.S. Pat. No. 3,952,750 of Mirowski et al (which discloses a command atrial cardioverting device). The utilization of an implantable automatic defibrillator is referred to in U.S. Pat. No. 4,030,509 to Heilman et al. Moreover, U.S. Pat. No. 4,164,946 to Langer discloses a fault detection circuit for a permanently implanted cardioverter.

Despite the developments of the recent past, there remains much room for advancement in this area of medical technology. For example, it is considered highly desirable to develop a single implantable heart stimulator having the capability of selectively performing any one of the various techniques for responding medically to recognizable heart disorders or arrhythmias, that is to say, the development of a single implanted heart stimulator capable of performing defibrillating, cardioverting, and pacing functions on a selective basis.

It also is highly desirable to develop an implantable heart stimulator and related method capable of selectively performing any one of these techniques on an automatic basis, that is, automatically in response to detection of the occurrence of the corresponding heart disorder or arrhythmia.

Moreover, an extremely advantageous feature of such a device and method would reside in the capability of externally programming the device to perform various operations, or sequences of operations, in accordance with defined parameters. Further elaboration on

this point, including a background discussion, is appropriate at this point.

It is known that the human heart requires coordinated electrical activity to successfully supply the body with a sufficient flow of blood. This coordinated activity is produced by a specialized conduction system contained in the body. A description of this system can be seen by reference to *The CIBA Collection of Medical Illustrations, Heart*, by Frank Netter, M.D., pp. 49-49, 1974 (ISBN 0-914168-07-X, Library of Congress Catalog No. 53-2151). Malfunctions of the conduction system produce a variety of human disease conditions up to and including death (see Netter, op. cit., pp. 66-68).

Recently, an implantable automatic defibrillator has been developed. The defibrillator automatically delivers a large electrical pulse to the fibrillating ventricles to abolish fatal malfunction and, thus, may be lifesaving in the case of ventricular fibrillation. Moreover, numerous other forms of electrical stimulation therapy have been, and are being, developed to treat various abnormalities of the heart.

For example, it is known that asystole (the absence of electrical stimulation to the ventricles of the heart) may be treated by implanting a pacer which periodically stimulates the ventricles with an electrical pacing pulse. Moreover, sophisticated pacing techniques, including various pacing modes (to be discussed in more detail below), have been developed.

Most automatic devices provide pulses to the atrium of the heart, but practitioners are reluctant to automatically treat the ventricle of the heart by pacing because of the dangers involved, for example, induced fibrillation. Accordingly, it is considered desirable to develop a device which has the capability of treating, by pacing modes and, if need be by backup defibrillation, any induced arrhythmia or fibrillation which might result from treatment of the ventricle of the heart.

It is presently known that electrical stimulation treatment modalities may be primarily classified in accordance with the energy level utilized, as follows:

Pulse Type	Energy Range
Pacing	equal to or less than 100 microjoules
Cardioverting or defibrillating (internal)	1-100 joules

Stated in simple terms, pacing pulses stimulate a very small volume of heart tissue (approximately 1-10 mm³), and the impulse is then contiguously conducted in a spreading fashion. Defibrillating pulses, on the other hand, are of sufficient strength to simultaneously stimulate all, or a critical mass, of the heart tissue, thus ameliorating the dangerous disorganized patterns of cyclic self-stimulation associated with ventricular fibrillation.

In the very recent past, combined pacing and cardioverting electrode systems have been developed, such as are described in U.S. Pat. No. 4,030,509 noted above. Such systems allow the delivery of defibrillating energy to either the atria or ventricles, and also allow for the delivery of pacing pulses. A large number of possible electrical stimulation options are thereby made possible from the combined electrodes.

Such combined pacing and defibrillating functions are quite effective in an implanted device because some symptoms, such as the absence of R-waves, could indi-

cate an asystole (treatable by pacing) or life-threatening ventricular fibrillation. It therefore would be desirable to have a combined pacer-defibrillator that first could attempt pacing in the presence of such symptoms, and then, if the symptoms persist, attempt defibrillation.

A further copending patent application, Ser. No. 902,763 of Langer et al, is directed toward the development of a data recording device, intended for implantation along with an implantable automatic defibrillator. The intended purpose is to record approximately 100 seconds of the heart's electrogram before, during and after an episode of ventricular fibrillation. At a later time, the stored information may be extracted to provide a complete, permanent record of the ventricular fibrillation episode, including the operation of the device during automatic defibrillation. The use of this recording capability may be extended to capture critical data for additional modes of electrical stimulation therapy, and also to gain information which could lead to more effective future electrical stimulation.

Pacers are increasingly becoming programmable, whereby parameters such as pulse rate, pulse amplitude and R-wave sensitivity may be adjusted from an external device in electromagnetic communication with the implanted pacer. It would be highly desirable to implant a microprocessor within an implanted pacer/cardioverter, for a communication link could thus be established to enter data, such as a new program, changing the software program (and, hence, operation) of the microprocessor. Moreover, the presence of a microprocessor would allow the use of extensive logic and analysis in the diagnosis and treatment of heart malfunctions with various regimens of electrical heart stimulation. Thus, it is considered highly desirable to develop an implantable heart stimulator capable of performing more than one mode of electrical heart stimulation for a given malfunction, and further provided with the capability of utilizing a variety of parameters within any given mode of operation, and even further with the capability of employing logic in a variety of fashions.

Further referring to the employment of a microprocessor in an implantable heart stimulator, it is to be recognized that various microprocessors available today vary in both power consumption and speed, thus making certain microprocessors (of lower power and speed) suitable for long-term operations, while other microprocessors (of higher power and speed) are more suitable for performance of sophisticated operations on a short-term basis. Accordingly, it is considered highly desirable to provide an implanted heart stimulator with a dual processor capability. It is also desirable to provide the heart stimulator with both a high power, high speed processor and a low power, low speed processor. This would especially be advantageous in view of the further design criterion of providing an implantable heart stimulator having multiple modes of operation for performing various electrical heart stimulation techniques (as discussed above), since some operations would be suitable for performance by one processor, while others would be more suitable for performance by the other microprocessor.

Finally, there are times, during operation, when it would be preferable for a given processor to operate at a speed higher than its normal speed of operation. Thus, it is considered highly desirable for an implantable, microprocessor-based heart stimulator to have the built-in capability of "gear shifting" so that the microprocessor operates temporarily at a higher speed of operation.

SUMMARY OF INVENTION

According to the present invention, there is provided an implantable heart stimulator and related method, and more particularly a highly versatile, efficient, and externally programmable heart stimulator which forms an integrated system for carrying out electrical heart stimulation techniques (defibrillation, cardioversion, pacing, etc.) in response to the detection of various heart disorders or arrhythmias. Such an implantable heart stimulator is processor-controlled, and is preferably controlled by dual processors, each of the two processors being specifically chosen, by virtue of its design, for controlling a particular type of operation (long-term versus short-term, simple versus sophisticated).

To be more specific, the present invention relates to an implantable heart stimulator and related method capable of performing in a multiplicity of operating modes, each of which can non-invasively be activated. In addition, as will be explained below, various parameters for each mode are externally programmable. The long-term operating modes, to be performed by a simpler, slower, and less power-consuming processor, basically comprise: (1) ventricular fixed rate pacing, (2) atrial fixed rate pacing, (3) ventricular demand pacing, (4) bifocal pacing, and (5) automatic defibrillation. A short description of each mode is appropriate.

In the ventricular fixed rate pacing mode, the parameters can be programmed to various values. Such pacer parameters include pulse rate, rate limit, pulse amplitude (milliamperes), and pulse width (milliseconds). In a preferred embodiment of the present invention, an override capability exists, allowing the attending physician to double pulse rates (up to an appropriate maximum number of pulses per minute, e.g., 200 pulses per minute) for the purposes of overdrive. By activating the override mode, a burst of high rate pulses for a period of two to three seconds is issued. After this burst, the override is deactivated automatically and the pacer parameters return to original values.

In the atrial fixed rate pacing mode, the parameters can be programmed to various values, the parameters including pulse rate, rate limit, pulse amplitude and pulse width. In addition, an override capability exists, allowing the attending physician to cause a burst of rapid atrial pacing. In this mode, pulse rates can be increased by a factor of 10 over typical pulse rates, (50, 55, . . . , 115, 120 pulses per minute). Such a burst will last between 2 and 3 seconds, after which the pacer parameters return to their original values.

In the ventricular demand pacing mode, parameters can be programmed to various values; the parameters include pulse rate, rate limit, pulse amplitude, pulse width, sensitivity, and refractory period.

In the bifocal pacing mode, the parameters can again be programmed to various values, the parameters including pulse rate, rate limit, pulse amplitude, pulse width, sensitivity, refractory and AV (atrioventricular) delay.

Finally, automatic defibrillator operations can be performed in accordance with conventional parameters, including pulse energy (joules), number of pulses per sequence, and energy of each pulse. See, for example, U.S. Pat. Nos. 3,952,750 and 4,030,509.

Short-term operating modes, to be performed by a sophisticated, high-speed (and thus, high power-consuming) processor include: cardioversion, automatic patient warning, and automatic ventricular tachycardia

control operations (including ventricular override pacing, rapid atrial pacing, ventricular coupled pacing, and automatic cardioversion). In addition, the more sophisticated and high-speed processor can perform, in a preferred embodiment, four-function recording, such recording being long-term in nature, but nevertheless performed by the high-speed processor, operating in the direct memory access (DMA) mode. A brief discussion of each of the latter operations is now appropriate.

In a preferred embodiment, the cardioversion mode is activated only by reception of an external command signal (such as detection of placement of a magnet on the surface of the skin adjacent to an implanted reed switch and the transmission of a word over the data channel). The output produced in the cardioversion mode is synchronized with the next R-wave following receipt of the command signal. Preferably, only one pulse per command is issued, and the pulse energies are non-invasively selected from among certain predetermined values (for example, 2, 5, 10, 15, 20, 25, 30 or 35 joules).

The automatic ventricular tachycardia control mode of operation is the most complex of all modes of operation implemented by the system of the present invention. This mode of operation can be implemented under program control, the implantable heart stimulator being pre-programmed and enabled by the physician. However, there exists also the capability of reprogramming the implantable heart stimulator, in correspondence to the results of the treatment thus far, and then enabling the operation of the heart stimulator so as to treat the patient further in accordance with the reprogrammed procedure. In this mode, any combination and/or sequence of the following sub-modes can non-invasively be selected (programmed) by the attending physician: ventricular overdrive pacing, ventricular coupled pacing, automatic cardioversion, and rapid atrial pacing. Any or all of these can be selected, so that, if the first response is not effective in controlling ventricular tachycardia, the next response is activated. That is, initially, a list associated with the various modes can be developed; then, the doctor can revise the list depending on the patient's reaction to treatment. A more detailed discussion of each of these sub-modes of operation now follows.

When ventricular tachycardia is detected, a two- to three-second burst of ventricular overdrive pacing is issued. The rate of overdrive pacing is pre-programmed at 10, 15, 20 or 25% above the sensed ventricular tachycardia rate. The number of bursts is pre-programmed at 1, 2, 3, or 4 before automatically proceeding to the next response mode. There is, typically, a five-second delay between bursts.

In the ventricular coupled pacing sub-mode, N ventricular pulses existing above a given rate cause a ventricular pacing pulse to be placed at a given time (expressed in percentage of the R-R interval) following the Nth ventricular pulse. In addition, if the tachycardia continues, a search mode comes into effect for which, after each Nth pulse, the coupling interval decreases by a given amount of time, until the final coupling interval is reached. This procedure can be repeated a number of times (preferably, up to four) before proceeding to the next response mode. Various parameters for this sub-mode of operation include the number of precursor pulses, the tachycardia rate (pulses per minute), the initial coupling interval (percentage of R-R interval), the coupling decrement (percentage), the final coupling

interval (percentage), and the number of response cycles.

In the automatic cardioversion sub-mode of operation, when ventricular tachycardia is detected, an output pulse synchronized with an R-wave is issued. Up to four such pulses may be issued with any combination of pre-programmed energies (for example, 2, 5, 10 or 15 joules) before proceeding to the next response mode. There is, typically, a 5 second delay between each cardioversion pulse.

Finally, in the rapid atrial pacing sub-mode of operation, a two- to three-second burst of rapid atrial pacing is issued at a pre-programmed rate. The number of bursts before proceeding to the next response mode are pre-programmed at 1, 2, 3 or 4. There is typically, a five-second delay between each burst.

As stated previously, four-function recording constitutes a mode of operation which, although long-term in nature, is performed by the short-term processor, operating in the DMA mode. Typical information to be recorded for various events includes times and dates of episodes (such as fibrillation episodes or defibrillation pulses in the absence of fibrillation), ten seconds of precursor ECG, capacitor charge times (for example, for each fibrillation pulse), ninety seconds of post-pulse (post-fibrillation pulse) ECG, and various other data, as required by the attending physician, such capability being readily available merely by externally pre-programming the implanted heart stimulator device.

A plastic warning mode of operation constitutes a further short-term mode of operation performed by the more sophisticated of the two processors. In accordance with this mode of operation, a patient warning pulse burst is issued upon detection of ventricular fibrillation. The parameters of this signal are programmable to optimize patient detection, such parameters including burst duration (preferably, rather short), burst amplitude, pulse width, and pulse rate. It is also considered desirable to program the implantable heart stimulator to include a service request pulse burst activated by device fault detection, loss of pacer capture or sensing, low battery voltage, and other similar conditions. The service request signal must be distinguishable from the warning signal, and could, for example, be constituted by two short bursts of a few seconds duration, occurring within ten seconds, and repeated once every hour with amplitude, width and rate programmable, as stated above.

Thus, the implantable heart stimulator and method of the present invention provide the capability of external programming so that various operations, or sequences of operations, can be performed in accordance with various parameters which are capable of being externally set at the discretion of the attending physician.

In general, the implantable heart stimulator according to the present invention comprises an input stage for receiving various status and sensor inputs, a controller section (preferably implemented by a microprocessor) for selectively performing any one of various operations of various types, an output stage responsive to signals provided by the controller for activating the various electrical heart stimulation devices (as well as for activating a patient warning system), and a data input/output channel for receiving and providing, to the controller, data inputs thereto, and for receiving from the controller and providing as an output various data outputs (for example, data to be displayed). In a preferred embodiment, the controller comprises a first controller for

selectively performing any one of various operations of a given type, a second controller for selectively performing any one of a plurality of operations of a different type, and an interface for providing exchange of information and control signals between the two controllers.

The implantable heart stimulator and method involve the determination of a condition, from a plurality of conditions, afflicting a patient, the choosing of at least one mode of treatment for treating the condition, and the execution of the steps of each mode or modes of treatment. In a preferred embodiment, the steps or functions just described are repetitively and continuously implemented by the stimulator of the present invention.

Finally, in one embodiment of the implantable heart stimulator and method, a sensing system is provided for sensing the absence of a natural R-wave, as a result of which pacing is performed, and then sensing the presence or absence of a forced R-wave (as would result from successful pacing), the system taking no action in the presence of a forced R-wave, or performing defibrillation in the absence of a forced R-wave.

Therefore, it is an object of the present invention to provide an implantable heart stimulator and method, and more particularly a multi-mode implantable heart stimulator and method capable of accomplishing various types of electrical heart stimulation in response to detection of the occurrence of various heart disorders or arrhythmias.

It is a further object of the present invention to provide a highly versatile implantable heart stimulator capable of performing defibrillation, cardioversion and pacing.

It is a further object of the present invention to provide an implantable heart stimulator which is microprocessor-controlled, and, further, which is externally programmable with respect to various operations, or sequences of operation, to be performed, and various parameters in accordance with which such operations are to be performed.

It is a further object of the present invention to provide an implantable heart stimulator which is not only microprocessor-controlled, but which is controlled by a plurality of processors (for example, in a preferred embodiment, two processors), each processor being specially selected, by virtue of its design, for performing operations of a given type.

It is a further object of the present invention to provide an implantable heart stimulator controlled by dual processors, one processor being specially selected and designed for the performance of long-term operations, simple in type, while consuming relatively low power, the other processor being selected for the performance of short-term, sophisticated operations, even though consuming relatively high power.

It is a further object of the present invention to provide an implantable heart stimulator controlled by at least one processor which is specially designed for normal operation at a given speed, and which can selectively be actuated to a higher processing speed for the performance of specialized operations requiring high speed of performance.

It is a further object of the present invention to provide an implantable heart stimulator having a data recording device capable of being implanted along with the implantable heart stimulator.

It is a further object of the present invention to provide an implantable heart stimulator and method,

wherein absence of a natural R-wave is sensed, as a result of which pacing is performed, followed by sensing of the presence or absence of a forced R-wave, with no further action being taken in the presence of a forced R-wave, and defibrillation being performed in the absence of a forced R-wave.

The above and other objects that will hereinafter appear, and the nature of the invention, will more clearly be understood by reference to the following description, the appended claims, and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram of the implantable heart stimulator of the present invention.

FIGS. 2A, B and C are diagrams relating to the input stage 12 of FIG. 1.

FIGS. 3A and 3B are diagrams relating to the controller 14 of FIG. 1.

FIG. 4 is a block diagram of the interface 16 and controller 18 of FIG. 1.

FIG. 5 is a block diagram of the output stage 22 of FIG. 1.

FIG. 6 is a flow chart of a typical program exemplifying the types of operations performed by the controller 14 of FIG. 1.

DETAILED DESCRIPTION

The present invention will now be more fully described with reference to various figures of the drawings, FIG. 1 of which is a block diagram of the implantable heart stimulator of the present invention.

As seen in FIG. 1, the implantable heart stimulator 10 comprises: an input stage 12 for receiving various sensor and status inputs, that is to say, an impedance sensor input derived from electrodes (not shown) connected to the heart, an electrocardiogram (ECG) input derived from conventional ECG detection and amplifier circuitry (not shown), and an external command signal ("magnet in place") alerting the implantable heart stimulator to the fact that an external command is being received by virtue of placement of a magnet in proximity to the skin, and thus in proximity to (for example) a reed switch (not shown) located just under the skin's surface; a controller (A) 14 which, in response to various signals and inputs received from the input stage 12, as well as from an interface 16 and controller (B) 18 (to be discussed below), performs various operations so as to generate different control and data outputs to both an interface 16 and an output stage 22; an interface 16 providing a conduit through which various data, status and control signals pass to and from input stage 12, controller 14 and controller 18; a second controller (B) 18 responsive to various data and control inputs received from input stage 12, interface 16, and a data input/output channel 20, for performing various operations to provide control and data outputs to the input stage 12, the controller 14, the interface 16, the data input/output channel 20, and the output stage 22; a data input/output channel 20 forming a conduit through which both data in and data out pass on their way to or from various elements (visibly, controller 14 and controller 18) of the implantable heart stimulator 10; and an output stage 22 responsive to various control signals from controller 14 and controller 18 for not only actuating conventional defibrillation, cardioverting and pacing devices connected thereto, but also for actuating a patient warning system (to be discussed below).

In accordance with a preferred embodiment of the present invention, controller 14 and controller 18 are specially selected, by virtue of their design, to perform certain, respective operations for which they are particularly suited. This feature of the present invention, including the precise breakdown of functions between controllers 14 and 18, will be discussed in more detail below.

FIGS. 2A, 2B and 2C are diagrams relating to the input stage 12 of FIG. 1. As seen therein, input stage 12 comprises amplifier and signal conditioning circuitry 30, converter 32, a dedicated cardiac state evaluation circuit 34, and an input selector 36.

In operation, amplifier and signal conditioning circuitry 30 receives an ECG input provided by conventional ECG detection circuitry, and performs amplification and signal conditioning (filtering) to provide an analog output. Furthermore, amplifier and signal conditioning circuitry 30 receives an input CONTROL WORD from the controller 18 (FIG. 1), which control input sets the corner frequency for differentiating the ECG input, and also sets the maximum gain which the amplifier can have (thus, setting the sensitivity for the ECG input).

The amplifier and signal conditioning circuitry 30 and the converter 32 of FIG. 2A are shown in more detail in FIG. 2B. As seen therein, the amplifier and signal conditioning circuitry 30 comprises filtering capacitor 298 and a differentiation circuit made up of amplifier 300 and resistor 302. The converter 32 comprises absolute value circuit 304, an RC circuit made up of resistor 306 and capacitor 308, a comparator 310, comparator 312, and comparator 314.

In operation, the input ECG signal is filtered by capacitor 298, and then is differentiated by amplifier 300 and resistor 302. The resulting differentiated ECG signal is provided to an absolute value circuit 304, resulting in generation of the absolute value of the differentiated ECG signal, waveform 318 in FIG. 2C.

The latter waveform is provided to a comparator 314, which receives a reference input REFA, by means of which an output RWAVE (waveform 320 in FIG. 2C) is generated so as to identify the occurrence of each R-wave.

The absolute value of the differentiated ECG signal from absolute value circuit 304 is provided as one input to comparator 312, the other input of which is a reference input REFB, REFB being lower in level than REFA. As a result, comparator 312 generates a further output WINDOW (waveform 316 of FIG. 2C), thus defining the extent of the waveform 318.

Finally, the differentiated ECG output from comparator 300 is provided, via RC circuit 306, 308, to one input of comparator 310, the other input of which is provided with a reference input REFC. As a result of its operation, comparator 310 generates an output PEAK REACHED, such output identifying each occurrence of a peak in the ECG signal.

Returning to FIG. 2A, dedicated cardiac state evaluation circuit 34 receives digital inputs RWAVE and WINDOW, and produces an interrupt command to the controller (A) 14 (designated INTERRUPT ON STATE). Dedicated cardiac state evaluation circuit 34 also generates, in response to detection of particular cardiac states, corresponding outputs indicating the occurrence of the particular state, that is to say, output FIB (indicating fibrillation), output TACHY (indicating tachycardia), and output BRADY (indicating bradycar-

dia). The latter three outputs are provided to input selector 36.

More specifically, the dedicated cardiac state evaluation circuit 34 comprises circuitry similar to the heart rate circuitry contained in the arrhythmia detection system disclosed in copending application Ser. No. 175,670 filed on Aug. 5, 1980 and fibrillation detection circuitry as in Pat. No. 4,184,493 of Langer et al. Thus, the dedicated cardiac state evaluation circuit comprises circuitry similar to that previously disclosed, such circuitry responding to the RWAVE and WINDOW data inputs thereto for determining which of three states (fibrillation, tachycardia or bradycardia) exists. Moreover, by conventional means (for example, by conventional OR gate circuitry), the dedicated cardiac state evaluation circuit 34 issues an output INTERRUPT ON STATE to the controller 14 whenever any one of the three conditions is detected.

It is also to be noted that conventional logic circuitry can be provided for determining, based on the previously discussed inputs, the existence of various medical conditions, for example, ventricular tachycardia, ventricular fibrillation and super-ventricular tachycardia. Such conventional logic circuitry can be provided either in the dedicated cardiac state evaluation circuit 34, or in one of the processors/controllers to be discussed below. The logic involved will, however, be discussed at this point.

Occurrence of FIB in the absence of TACHY indicates the occurrence of a low-rate tachycardia condition. Conventional medical technique calls for no electrical shock to be administered to a patient afflicted with this condition. However, under these conditions, a "wake-up" call to the controller 18 is issued via the interface 16 and sophisticated pacing modes may begin if so programmed.

Occurrence of both FIB and TACHY indicates a ventricular fibrillation condition, and again a "wake-up" signal is sent to the controller 18 via the interface 16. In addition, controller 14 (FIG. 1) is actuated to cause a defibrillation shock to be issued to the patient via the output stage 22. More specifically, and as will be discussed below, the controller 14 fetches the energy required for defibrillation from a parameter memory (also to be discussed below), transmits such information to a defibrillation pulse generator, shuts down pacing circuits, and issues various other control outputs so as to cause a defibrillation shock to be built up and then applied to the patient (as opposed to a test load). The controller 18, during this time period, is involved in recording parameters surrounding the issuance of the defibrillation shock, such data being provided to the controller 18 via the data input/output channel 20 (FIG. 1).

It is to be noted that, during defibrillation shock of the patient, a sync output is provided to the output stage 22 (specifically, to a pulse generator contained therein) from the interface 16 (specifically, from an output latch contained therein) so that a determination can be made as to whether or not the pulse generator is synchronized (for example, synchronized with RWAVE). Thus, the sync line is kept high at all times during ventricular defibrillation.

Occurrence of output TACH in the absence of output FIB indicates a super-ventricular tachycardia condition, that is, a condition during which the heart beat is rapid but the known probability density function criteria is not fulfilled. In such an instance, synchronized

cardioversion (that is, cardioversion synchronized with the RWAVE) may be indicated. Accordingly, under such conditions, a mode word contained in a parameter memory (associated with the controller 18) is provided to an input selector (contained within controller 14), such input selector (as will be discussed in more detail below) basically comprising a one-bit processor unit. The controller 14, as will also be explained in more detail below, issues sync pulses which, when high, indicate synchronization with the R-wave. As a result of such sync pulses provided to the output stage 22 (which contains a pulse generator), a voltage is built up and a pulse is issued once SYNC goes "high".

The latter operations will be discussed in more detail below, in connection with a discussion of the detailed diagrams for the controller 14, interface 16, controller 18, data input/output channel 20 and output stage 22 of FIG. 1.

Input selector 36 is, as previously stated above, a single-bit processor which receives the various control inputs previously mentioned (RWAVE, WINDOW, PEAK REACHED, FIB, TACHY and BRADY), as well as other control inputs (MAGNET IN PLACE, TIMER A OVER, TIMER B OVER) generated outside of the input stage 12. In addition, input selector 36 receives and provides various status and control signals from and to, respectively, the controller (A) 14, and receives data from and provides data to the interface 16. Finally, input selector 36 receives address data from the controller 14.

In response to control inputs from the controller 14, input selector 36 selectively routes the aforementioned control inputs (FIB, TACHY, etc.) from the evaluation circuit 34 to the controller 14. Input selector 36 is, as previously mentioned, an input selector for the one-bit processor, otherwise known as a multiplexer chip (for example, a CMOS chip, model no. 14512). Additional functions of the input selector 36 will be described below, as the implantable heart stimulator and method are described in more detail.

FIGS. 3A and 3B are diagrams relating to the controller (A) 14 of FIG. 1. Controller 14 comprises a microprocessor (A) 40, a program counter 42, program memory 44, program counter preset 46, timer (A) 48, and timer (B) 50.

Microprocessor 40 is, preferably, a control unit of the type generally designated as MC14500B (manufactured by Motorola). However, for the purposes of making and using the present invention, microprocessor 40 may be any similar unit capable of performing relatively simplistic functions on a long-term basis, while consuming relatively low power; e.g., discrete logic can be employed. Microprocessor 40 performs its operations under program control in response to sequentially received operation codes (preferably, of four bits) from the program memory 44.

The microprocessor 40 receives various status and/or control inputs from input stage 12 (specifically, from input selector 36 thereof, as previously discussed), as well as from interface 16 (to be discussed below). Thus, microprocessor 40 need only be capable of reading (and, of course, responding to) such one-bit control inputs. For example, as previously mentioned, microprocessor 40 responds to control input FIB, TACHY and BRADY (provided via input selector 36) to perform the various logic operations discussed above, and to produce corresponding outputs VT, VF and SVT indicating the occurrence of ventricular tachycardia,

ventricular fibrillation and super-ventricular tachycardia, respectively.

In addition, in response to such control inputs, and as dictated by the program stored in memory 44, microprocessor 40 performs various other sequential operations (to be discussed in detail below), and in the process generates various control outputs (preferably, one-bit outputs). Notably, microprocessor 40 generates the following control outputs having the indicated functions:

JMP/PRESET—a control output provided to program counter 42 for causing the counter 42 to jump to a given value, thus establishing a given address in memory 44 which is to be accessed for the purpose of providing a given sequence of instructions (op codes) to the microprocessor 40. JMP/PRESET is generated under program control, and causes the "jump address" from preset 46 to be locked into program counter 42. More specifically, the JMP/PRESET command permits execution of a "jump" instruction in accordance with a stored program executed by the controller 14. The program counter preset 46 provides a "jump address" to the program counter 42, the program counter preset 46 consisting of a set of registers (for example, tristate buffers) having low-order bits which define the address bus from program memory 44. It is to be noted that high-order bits which define the address latch (the page to which a jump is to be executed) are provided as input **PAGE INDICATOR** by evaluation circuit 34 to processor 40. At this juncture, a discussion of the program memory 44 is appropriate.

As seen in FIG. 3B, the program memory 44 may be divided into convenient blocks (for example, of 256 bits size), with each block or page of memory being reversed for a program dealing with a particular one of the conditions which can be experienced by a cardiac patient. Thus, the first block might contain the program for executing a pacing mode, the second block may contain the program for treating a person in need of cardioversion, a third block may contain the program for treating a person in need of defibrillation, and so forth. As mentioned above, the high-order bits of the "jump address" (**PAGE INDICATOR**) are provided to processor 40 by evaluation circuit 34, and correspond to the particular page or block of memory (set of instructions dealing with a particular condition) to be executed.

Thus, referring back to the discussion of controller 14, with reference to FIGS. 2A and 3A, detection of one of the cardiac conditions by the dedicated cardiac state evaluation circuit 34 results in transmission of control signal **INTERRUPT ON STATE** to the program counter 42 of controller 14 (FIG. 3A) causing generation of **PAGE INDICATOR**. The program counter 42 responds to **INTERRUPT ON STATE** by resetting the low-order bits of the memory address, while **PAGE INDICATOR** establishes the high-order bits which enable the program counter 42 to page to the beginning of that block in memory 44 corresponding to the desired treatment. Then, the microprocessor 44 responds to successive op codes from the program memory 44 so as to execute the program corresponding to the desired treatment (pacing, cardioversion, defibrillation, and so forth).

CLOCK—a clock-type output provided by microprocessor 40 to the program counter 42, in accordance with which program counter 42 cycles through succes-

sive addresses so as to access successive locations in the program memory 44.

WRITE—a pulse output generated by microprocessor 40, and provided to the interface 16. More specifically, whenever the microprocessor 40 in controller 14 determines that data must be provided to certain other elements of the implantable heart stimulator, it issues the **WRITE** command to the interface 16 (specifically, to an output latch contained therein, and to be discussed below). The interface 16 responds by providing whatever data is contained on the address bus connected to the output latch in interface 16 to the appropriate element (for example, the timers 48 and 50, which receive timer data from the interface 16 (the output latch contained therein)).

An example of such a procedure is as follows: (1) an address (**ADDR**) is provided from the program memory 44 to the timers 48 and 50 so as to select one of the timers, and to the interface 16 (the output latch contained therein) so as to access data (e.g., **TIMER VALUE**) in parameter memory 58; (2) the latch responds thereto by accessing the particular address in parameter memory 58, which address contains the data to be transferred; (3) the desired data (for example, timer address data) is made available, via the output latch in interface 16, to the timers 48 and 50; (5) a selected timer, as indicated by the timer address data (**ADDR**) provided by the program memory 44 to the timers 48 and 50, receives the data (**TIMER VALUE**) made available by the interface 16; and (6) the particular timer 48 or 50 begins its timing operation. In this manner, such timing information as the atrial escape interval (related to the pacing rate) or ventricular escape interval can be provided, and a timing operation can be conducted in accordance therewith, so as to accomplish various pacing or defibrillation functions. It is to be noted that, as an alternative, an enable signal **TIMER ENABLE** from controller 18 could be used to select/enable a given one of the timers 48 and 50.

FLAGO—a control output provided to the interface 16. This control output is used as a strobe to write information into an address latch contained within the interface 16.

STATUS/CONTROL—a general designation for status and control inputs received from and provided to input stage 12; more specifically, various status and control signals selected by input selector 36 (as previously discussed) are provided to the microprocessor 40 of controller 14. These status and control signals relate, for example, to the various medical conditions which might occur: tachycardia, bradycardia, fibrillation, and so forth, as already discussed.

Further referring to FIG. 3, it is to be noted that microprocessor 40 receives a control input **HIGH CLOCK** from the interface 16. The microprocessor 40 responds to this "high clock" instruction so as to switch its mode of operation into "high gear" in order to perform subsequent processing operations at a higher speed than is normally the case. Conversely, the microprocessor 40, in the absence of the "high clock" instruction, operates in a "low gear" mode of operation so as to perform processing operations at a lower speed, that is, at a normal speed of operation. In this manner, those operations which require high speed of operation can be performed with such high speed of operation, while those operations which may be performed at normal speed may be performed at normal speed of operation,

thus saving power by adapting the processing speed to the particular operation being performed.

Finally, microprocessor 40 receives data from and provides data to the interface 16. More specifically, data is transmitted between the microprocessor 40 and the interface 16 by means of a standard data bus, the data line or bus consisting of a line or lines between the microprocessor 40 and a latch in the interface 16. Various positions in the latch are set/reset as determined by the address bus from the program memory 44 to the interface 16. Furthermore, one or more lines are provided between the controller 14 and the input selector 36 (FIG. 2A) so as to pass data from the input selector 36 to the microprocessor 40 (FIG. 3A) during a "read" operation.

As stated previously, program counter 42 is a conventional counter for issuing successive count outputs, derived in accordance with a clock input from the microprocessor 40. Thus, counter 42 accesses successive locations in the program memory 44 for the purpose of providing op code instructions to the microprocessor 40, as well as for the purpose of providing memory addresses to the input stage 12, specifically, to the input selector 36, thus causing input selector 36 to read the desired input line (e.g., **FIB**, **BRADY**, etc.) to the interface 16 covered previously, and to the timers 48 and 50 covered previously.

Finally, controller 14 includes a preset circuit 46 which (as previously explained) provides a **JUMP ADDRESS** output to the program counter 42 to preset the counter 42, thus executing a "jump" instruction.

FIG. 4 is a block diagram of the interface 16 and controller 18 of FIG. 1. As seen therein, the interface 16 comprises an output latch 52 and an address latch 54, both of which were referred to previously. They are conventional latches having multiple positions which can be set by controller 14 and/or input stage 12.

In operation, the output latch 52 effectively receives various control and data inputs from and provides various control and data inputs to the controller 14, receives various data from and provides various data to the input stage 12, and provides various control outputs to the controller 18 and output stage 22, respectively. More specifically, output latch 52 receives or provides the following control signals:

WRITE—a control input (discussed above) which is received from the controller 14, specifically, from microprocessor 40, and which causes the latch 52 to receive/store the data coming from the **DATA** line, that is, from the microprocessor 40 (FIG. 3A).

HIGH CLOCK—a control output (also discussed above) from output latch 52, which control output causes the microprocessor 40 to perform certain processing operations at a speed higher than normal, with other processing operations being performed at a normal speed, thus conserving power by adapting the speed of processing to the particular operation being carried out.

START DEFIB—a control signal generated by output latch 52 by command of the microprocessor 40, and provided to the output stage 22 (to a pulse generator therein), for the purpose of indicating the need for defibrillation. This control input is generated as a result of logical operations performed in the microprocessor 40; such logical operations were described above with reference to the various control input conditions (**FIB**, **TACHY**) which are logically processed so as to determine which medical condition (ventricular tachycardia

(VT), ventricular fibrillation (VF), or super-ventricular tachycardia (SVT)) has occurred.

AP1—a control output provided by latch 52 to the output stage 22, indicating the need for atrial pacing activity to take place; it is a control output generated by microprocessor 40.

VEP1—a control output provided by latch 52, and provided to output stage 22, indicating the need for commencement of ventricular pacing activity; it is a control output generated by microprocessor 40.

SELECT PATIENT—a control output generated by latch 52, and transmitted to output stage 22, designating the patient (as opposed to test load), with respect to which defibrillation activity is to be started (per the START DEFIB control signal previously discussed above).

WAKE UP—a control input generated by latch 52, and transmitted to the controller 18 for the purpose of alerting the controller 18 to perform its various control functions (as will be discussed below).

The output latch 52 receives, as previously stated, address data from the controller 14. Output latch 52 also receives data from and provides data to the input state 12, that is, to the input selector 36.

Address latch 54 of interface 16 receives address data and the control input FLAGO from controller 14, and provides parameter address information to the controller 18.

Further referring to FIG. 4, the controller 18 comprises a microprocessor (B) 56 and a pacer-defibrillator parameter memory 58. The microprocessor 56 is, preferably, a microprocessor system 1802 (manufactured by RCA Corporation), but can be any conventional microprocessor capable of performing similar operations. Typically, microprocessor systems capable of sophisticated operations consume relatively high power. The microprocessor 56 should, in accordance with the invention, have the capability of operation in the direct memory access (DMA) mode, such mode of operation being employed in the operation of a precursor memory. More specifically, the processor 56 has a DMA mode, by means of which ECG data is written into a precursor memory, so that the implantable heart stimulator can "look at" the ECG data just prior to fibrillation. This technique is known to those of skill in the art, especially in view of prior application U.S. Ser. No. 902,763 filed on May 3, 1978, now U.S. Pat. No. 4,223,678.

In the latter regard, in operation, the microprocessor 56 periodically executes DMA cycles so as to store ECG data in the precursor memory, such operation being carried out even while the microprocessor 56 is "asleep".

When defibrillation is detected by the microprocessor 40 (FIG. 3A) in controller 14, the precursor memory is "frozen", such that ECG information occurring just prior to defibrillation is available to the microprocessor 56, and thus to the operator of the implantable heart stimulator.

Microprocessor 56 generates, in response to the occurrence of certain conditions, a "patient warning" output, the latter being provided to output stage 22 for the purpose of generating a patient "tickle" signal. Microprocessor 56 also generates outputs AP2 (indicating the need for atrial pacing) and VP2 (indicating the need for ventricular pacing), the latter being provided to output stage 22.

Microprocessor 56 receives a control input, MAGNET IN PLACE, indicating an external command via the placement of a magnet in proximity to a reed switch (not shown) located just under the skin of the patient. This external command to the microprocessor 56 alerts it to the imminent input/output of data, and causes the microprocessor 56 (which is responsible for input/output of data to/from the implantable heart stimulator) to enable the data input/output channel 20 (FIG. 1). In this manner, the processors 40 and 56 can be reprogrammed, or a status word in the parameter memory 58 can be modified. For example, such a status word is provided in the memory 58 for the purpose of indicating which medical procedures (pacing, defibrillation, etc.) are appropriate and permissible for treating a particular patient. Thus, the use of the MAGNET IN PLACE command permits the physician or operator of the implantable heart stimulator to modify the status word in parameter memory 58, and thus modify the particular regimen of treatments which are permissible for the particular patient.

The pacer-defibrillator parameter memory 58 stores parameters necessary for performance of the pacer and defibrillation operations, as is conventionally known. For example, parameter memory 58 stores information relating to the energy magnitude to be utilized in conjunction with defibrillation, as well as information relating to atrial current and ventricular current to be utilized by the atrial pacer drive circuit 66 and the ventricular drive circuit 68, respectively, in conjunction with pacing operations. As stated previously, the address latch 54 in the interface 16 provides various parameter address information to the parameter memory 58, causing selective access of the memory 58 for the purpose of reading out parameter words. The parameter words are, as indicated in FIG. 4, provided to the controller 14 and to the output stage 22. As indicated earlier, these parameter words are provided to the timers 48 and/or 50 in controller 14 for the purpose of setting a destination count in the particular timer so that, when the timer is actuated for counting, a particular interval of time (for example, an AV delay period) will be measured, as a result.

More particularly, the controller 14 (FIG. 3A) includes timers 48 and 50 which are utilized to perform specific timing operations for specific medical treatments. For example, timer 48 could be used for timing the absolute refractory, while timer 50 could be used for timing the pacing (A-V) interval. Timers 48 and 50 each receive address information (ADDR) from the program memory 44, by means of which one or the other timer (or both timers) is (are) selected for carrying out a timing operation. Alternatively, the output latch 52 in interface 16 (FIG. 4) could be utilized to provide a TIMER ENABLE signal to each of the timers 48 and 50, so as to select one or the other (or both) for a timing operation. Finally, the parameter memory 58 in controller 18 provides TIMER VALUE data to each of the timers 48 and 50, such data representing the particular timing values to which the respective timers 48 and 50 are to count.

As indicated, the parameter words are also provided to the output stage 22. For example, parameter words defining energy magnitudes, in accordance with which the defibrillation activities are to be performed, are provided to appropriate circuitry in the output stage 22 (this will be discussed in more detail below, referring to FIG. 5).

It is to be noted that the parameter memory 58 is preferably a dual-port memory or a double-buffered memory. This is desirable in order that the parameters stored in memory remain stable insofar as the processors 40 and 56 are concerned, even while updating procedures are taking place. That is to say, the utilization of a dual-port or double-buffered memory precludes the occurrence of extreme changes in the parameters during ongoing medical procedures, which changes could cause the processors 40 and 56 to function erratically, with possible harm to the patient.

FIG. 5 is a block diagram of the output stage 22 of FIG. 1. As seen in FIG. 5, output stage 22 comprises inverter 62, pulse generator 64, atrial pacer drive circuit 66, ventricular pacer drive circuit 68, and patient warn-

ing circuit 70. In operation, output stage 22 causes the commencement of defibrillation activities in response to the reception, by inverter 62, of the START DEFIB input, provided (as previously discussed) by the output latch 52 of interface 16 (FIG. 4). The START DEFIB input is set by the processor 40 when defibrillation is deemed to be necessary, as previously explained. In response to the START DEFIB input, inverter 62 causes the pulse generator 64 to generate the required defibrillation pulses for transmission to electrodes on or in proximity to the heart (not shown). More specifically, pulse generator 64, in response to inverter 62, generates a defibrillation pulse having an energy magnitude as dictated by the parameter word provided by controller 18, more specifically, by the parameter memory 58 thereof (FIG. 4).

It is to be noted that further detail relative to the inverter 62 and pulse generator 64 in output stage 22 (FIG. 5) is believed to be unnecessary, since the performance of defibrillation techniques utilizing an inverter 62 and a pulse generator 64 are well-known in the art. For example, see prior application Ser. No. 464,180 filed on Apr. 25, 1974, now U.S. Pat. No. 3,952,750, and copending application Ser. No. 65,228 filed on Aug. 9, 1979.

The atrial pacer drive circuit 66 responds to reception of either signal AP1 (from the output latch 52 of interface 16) or the output AP2 (from the microprocessor 56 of controller 18), as received by an OR gate 72, to generate an atrial pace output to a pacer interface (not shown). Similarly, ventricular pacer drive circuit 68 responds to reception of either VP1 (from the output latch 52 of interface 16) or output VP2 (from the microprocessor 56 of controller 18), as received via an OR gate 74, to generate a ventricular pace output to the pacer interface (not shown).

It is to be noted that such a pacer interface is disclosed in copending application Ser. No. 193,027 filed on Sept. 30, 1980, and entitled "Method and Apparatus for Combining Defibrillating and Pacing Functions in a Single Implanted Device", assigned to the assignee of the present invention.

It is also to be noted that, with respect to atrial and ventricular pacing, as carried out by the implantable heart stimulator of the present invention, the output latch 52 of FIG. 4 and the microprocessor 56 of FIG. 4 are each equipped to handle both atrial and ventricular pacing. The specific one of these two elements which performs the atrial or ventricular pacing is dependent on the particular type of pacing to be performed. As mentioned above, the microprocessor 40 (FIG. 3A) operates in conjunction with the output latch 52 to

implement atrial and ventricular pacing involving long-term, relatively simple procedures. Conversely, the microprocessor 56 (FIG. 4) handles atrial and ventricular pacing involving short-term, relatively more complicated procedures.

Finally, the patient warning circuitry 70 responds to the reception of a patient warning input (from the controller 18) so as to generate a patient "tickle" signal, alerting the patient that defibrillation is about to take place. Patient warning circuit 70 could, thus, be any conventional circuit for generating a patient "tickle" or similar signal for the purpose of warning the patient of imminent defibrillation.

FIG. 6 is a flowchart of a typical program for implementing the operations of the microprocessor 40 of controller 14 of FIG. 3. In this particular instance, the program relates to simple pacing operations (bifocal pacing) performed under the control of microprocessor 40 of controller 14.

Referring to FIG. 6, block 100, the program is commenced by writing the address of the refractory period to the address latch, such information being provided as input ADDRESS DATA from the controller 14 to the address latch 54 (FIG. 4). In addition, the output FLAGO is toggled by the microprocessor 40 (FIG. 3), such control output being provided to the interface 16.

Further referring to FIG. 6, block 102, the absolute refractory period from parameter memory 58 (FIG. 4), as accessed by the address latch 54 (under the influence of ADDRESS DATA), is loaded in timer 48 (FIG. 3).

Referring to block 104, a decision is then made as to whether FLAGO is zero or one. Dependent on which of the two conditions exist, blocks 106 or 108 is implemented so as to write an appropriate address of the pacing interval to the address latch 54. Then, referring to block 110, the appropriate pacing interval is written to the timer 50 (FIG. 3).

Referring to FIG. 6, the logical operation indicated in block 112 is executed, and the program "loops" (blocks 112 and 114) until TIMER A OVER is generated by the time 48 (FIG. 3). As previously stated, this condition is detected by the controller 14 (FIG. 3) via input selector 36 (FIG. 2). Once TIMER A OVER is generated, the microprocessor 40 decides whether or not an R-wave has occurred (block 116). If such has occurred, the "paced beat" flag is cleared (block 118), and a return to block 100 is executed.

The "paced beat" flag can be implemented by merely allocating a particular memory location (one-bit memory location). Alternatively, a one-bit position in output latch 52 can be set aside as the "paced beat" flag, and such flag can be set or cleared by microprocessor 40 (FIG. 3A).

Returning to consideration of FIG. 6 (block 118), if the R-wave has not occurred, the address, in parameter memory 58, of the atrial current is provided to address latch 54, and the atrial current information is loaded from parameter memory 58 to the atrial drive circuit 66 in output stage 22 (FIG. 5), as indicated in block 120 of FIG. 6. Then, referring to block 124, the address, in parameter memory 58, of the pacing pulse width is written to the address latch 54, and the parameter memory 58, as addressed by latch 54, provides the pacing pulse width information to the timer (A) 48 (FIG. 3). However, as indicated in block 124 of FIG. 6, timing of the pacing pulse width by timer 48 is achieved in accordance with 10× (ten times) clocking. That is to say, the programmed operation of microprocessor 40 (FIG. 3)

causes the microprocessor 40 to transmit a control signal to the output latch 52 in interface 16 (FIG. 4). Output latch 52 then generates HIGH CLOCK, the latter being provided to the microprocessor 40 so as to cause it to "gear shift", and microprocessor 40 thus enters the mode of operation whereby processing takes place at a higher than normal speed of operation.

Referring to block 126, the address of the AV (atrial-to-ventricular) pulse delay period is written to address latch 54, and the parameter memory 58, as accessed by address latch 54, writes the AV pulse delay to timer (B) 50 (FIG. 3). Then, referring to blocks 128 and 130, the output latch 52 (FIG. 4) is set, so as to generate output AP1 (provided to the atrial pacer drive circuit 66 via OR gate 72 (FIG. 5)). The output latch 52 remains set so as to generate AP1 until the pacing pulse width set in timer 48 (FIG. 3) is completed. Then, the output latch 52, that is, output AP1, is cleared (block 132), and remains cleared until the AV pulse delay, set in timer 50, is completed (block 134).

Once the AV pulse delay period is completed, a further decision (block 136), as to whether or not the R-wave has occurred, is made. If the R-wave has not occurred, the address, in parameter memory 58, of ventricular current is written to the address latch 54, and parameter memory 58, once accessed by the address latch 54, provides the ventricular current information to the ventricular pacer drive circuit 68 via the OR gate 74 (FIG. 5), as indicated in block 138 of FIG. 6. Then, as indicated by block 140, the address of the pacing pulse width is written to address latch 54 (FIG. 4), and the parameter memory 58 provides the pacing pulse width to the timer (A) 48 (FIG. 3), the latter operating in the "gear shift" or "high clock" mode.

Further referring to FIG. 6, block 142, output latch 52 (FIG. 4) is set so as to generate output VP1, provided to the ventricular pacer drive circuit 68 via OR gate 74 (FIG. 5), and the output latch 52 remains set so as to continuously generate output VP1 until TIMER A OVER occurs at the output of timer 48 (FIG. 3), as indicated by the decision block 144 of FIG. 6. Referring to block 146, once TIMER A OVER is generated, the output latch 52 is cleared, so that output VP1 is no longer applied to the ventricular pacer drive circuit 68 (FIG. 5). Then, referring to block 148, the "paced beat" flag is set to select the proper pacing interval to allow for hysteresis. Hysteresis relates to a change in the pacing rate depending on whether previous beats from the heart were spontaneous or paced. Thus, when previous beats from the heart were paced, the "paced beat" flag (a predesignated memory location or, alternatively, a one-bit position in output latch 52, as discussed above) is set. In this manner, the implantable heart stimulator is able to remain aware of whether or not the previous heart from the heart was spontaneous or paced, thus allowing for hysteresis.

It is to be noted that, referring to block 136 of FIG. 6, if the R-wave has occurred (once TIMER B OVER is generated by the timer 50, as indicated by a "yes" branch from decision block 134), an immediate branch to block 148 is executed, so that the "paced beat" flag is set to select the proper pacing interval to allow for hysteresis. In any event, once block 148 is executed, a branch to the beginning of the pacing routine (block 100) is executed.

As pointed out earlier, there are certain symptoms, such as the absence of R-waves, that could indicate either ventricular fibrillation or asystole. Because of the

desirability of providing protection against both these conditions, a sensing system for ventricular fibrillation can, in one embodiment of the inventive method and system, be provided. For example, such a sensing system can comprise two R-wave detecting circuits. The first R-wave detecting circuit is preferably part of the pacer circuit, and, upon detecting the absence of valid R-waves, sends out pacer spikes in an effort to pace the heart.

Thus, in the case of asystole, the heart would respond by being paced, and would thus develop valid R-waves (forced R-waves) in response to the pacing stimuli. These R-waves are then sensed by a second R-wave detecting circuit (in the sensing system), this second R-wave detecting circuit subsequently controlling a defibrillating sub-system. Thus, in the event of ventricular fibrillation, the operation of the first R-wave detecting circuit in conjunction with the conventional pacing circuit would cause the generation of pacer spikes, but, due to the ventricular fibrillation condition, the heart would be unable to respond to the pacing stimuli. In that eventuality, the second R-wave detecting circuit would note the absence of valid, forced R-waves, and would then diagnose the condition as ventricular fibrillation.

In such an embodiment, an appropriate number of spikes from the second R-wave detecting circuit could be utilized to determine the time of release of the defibrillatory shock. For example, such a shock could be delivered after the twentieth (20th) spike corresponding, for example, to twenty (20) seconds, presuming that each spike is one (1) second apart.

It should be noted that, in such a scheme, the second R-wave detecting circuit must be precluded from responding to the pacing spike of the original pacing unit. This could be accomplished by using an appropriately oriented diode to keep the pacing spikes of the pacing unit (operating in conjunction with the first R-wave detecting circuit) from entering the second portion of the sensing system, that is, the second R-wave detecting circuit. This would, however, cut out half of the signal, and might lead to a problem with certain rhythms having predominantly monophasic complexes.

In the latter regard, it is considered possible to filter out the pacer spike by means of a low-pass filter, thus preventing the spike from getting into the second R-wave detecting circuit. Alternatively, one might choose to protect the amplifier of the second R-wave detecting circuit from the pacer spike by shorting the input thereof during the elaboration of the spike. Indeed, the spike itself could be used to indicate the shorting of the amplifier input, thus ensuring that the second R-wave detecting circuit monitors only during that time when a spike is not present.

In summary, of the three main possibilities or conditions, normal sinus rhythm would cause both the first and second R-wave detecting circuit to remain quiet. Asystole would cause the first R-wave detecting circuit to recognize the absence of R-waves, and the pacer circuit would elaborate spikes causing the paced QRS complexes to occur. If pacing succeeds, the second R-wave detecting circuit would recognize the valid, forced R-waves, and would inhibit further action. However, if pacing does not succeed, the pacer spikes would not cause valid, forced R-waves (indicating ventricular fibrillation), and this condition would be sensed by the second R-wave detecting circuit. As a result, the latter would activate the defibrillation circuit, and would be

used to control subsequent defibrillatory shocks, as indicated above.

It is obvious that the embodiments of the present invention described hereinabove are merely illustrative and that other modifications and adaptations thereof 5 may be made without departing from the scope of the appended claims.

What is claimed is:

1. A method of heart stimulation using an implantable heart stimulator capable of detecting a plurality of arrhythmias and capable of being programmed to undergo a single or multi-mode operation to treat a detected arrhythmia, corresponding to said mode of operation the method comprising the steps of:

- (a) determining a condition of the heart from among a plurality of conditions of the heart;
- (b) selecting at least one mode of operation of the implantable heart stimulator which operation includes a unique sequence of events corresponding to said determined condition; and
- (c) executing said at least one mode of operation of said implantable heart stimulator thereby to treat said determined heart condition.

2. The method of claim 1, further comprising the step (d) of repeating said steps (a)-(c), whereby to continuously monitor and treat determined heart conditions.

3. The method of claim 1, wherein said at least one mode of operation of said implantable heart stimulator includes a cardiac pacer mode of operation.

4. The method of claim 1, wherein said at least one mode of operation of said implantable heart stimulator includes cardioversion.

5. The method of claim 1, wherein said at least one mode of operation of said implantable heart stimulator includes automatic defibrillation.

6. The method of claim 1, wherein said at least one mode of operation of said implantable heart stimulator comprises a plurality of unique modes of operation of said implantable heart stimulator corresponding to respective arrhythmias, said method further comprising the step of providing said implantable heart stimulator with dual processors, one of said dual processors being designed to efficiently implement a first group of said plurality of modes of operation of said implantable heart stimulator, and a second one of said dual processors being designed to efficiently implement a second group of said plurality of modes of operation of said implantable heart stimulator.

7. The method of claim 1, wherein said implantable heart stimulator is microprocessor-controlled, said method further comprising the step of externally programming said microprocessor-controlled implantable heart stimulator with respect to said at least one mode of operation thereof.

8. The method of claim 1, wherein said implantable heart stimulator is capable of operation in a cardiac pacer mode of operation and an automatic defibrillation mode of operation;

said step (a) comprising determining the presence or absence of a naturally induced R-wave of the heart rhythm;

said step (b) comprising selecting said cardiac pacer mode of operation;

said step (c) comprising executing said cardiac pacer mode of operation to pace the heart;

said method comprising the further steps of:

- (d) determining the presence or absence of a forced R-wave;

(e) selecting, in the absence of said forced R-wave, the automatic defibrillation mode of operation; and

(f) executing, in the absence of said forced R-wave, said automatic defibrillation mode of operation to automatically defibrillate the heart.

9. The method of claim 8, wherein said step (e) further comprises, in the presence of a forced R-wave, returning to said step (a).

10. An implantable heart stimulator capable of monitoring and detecting a plurality of arrhythmias, and capable of being programmed to undergo a single or multi-mode of operation corresponding to a respective arrhythmia to treat automatically the detected arrhythmia, said stimulator comprising:

determining means for determining the occurrence of one of a plurality of conditions of the heart;

selecting means responsive to said determining means for selecting at least one mode of operation of said implantable heart stimulator corresponding to a respective one of said plurality of conditions for automatically treating said determined conditions; and

executing means for executing a sequence of events defined by said at least one mode of operation, whereby to treat said determined condition.

11. The stimulator of claim 10, wherein said implantable heart stimulator continuously monitors the heart in order to determine the occurrence of any said plurality of conditions.

12. The stimulator of claim 10, wherein said at least one mode of operation includes cardiac pacing.

13. The stimulator of claim 10, wherein said at least one mode of operation includes cardioversion.

14. The stimulator of claim 10, wherein said at least one mode of operation includes automatic defibrillation.

15. The stimulator of claim 10, wherein said determining means comprises a first detecting circuit for detecting presence or absence of a naturally induced R-wave of the heart, and a second detecting circuit for detecting presence or absence of a forced R-wave of the heart, said selecting means being responsive to absence of said natural R-wave for selecting a cardiac pacer mode of operation, said executing means being responsive to selection of said cardiac pacer mode of operation for pacing the heart, said selecting means being responsive to absence of said forced R-wave for selecting an automatic defibrillation mode of operation, said executing means being responsive to selection of said automatic defibrillation mode of operation for automatically defibrillating the heart.

16. The stimulator of claim 15, wherein said second detecting circuit is actuated to detect the presence or absence of said forced R-wave only after selection and execution of said cardiac pacer mode of operation.

17. The stimulator of claim 16, wherein said selecting means responds to detection of said forced R-wave by inhibiting execution of said automatic defibrillator mode of operation.

18. The stimulator as recited in claim 10 further including a programmable control store for defining a sequence of electrical events corresponding to at least one mode of operation and corresponding operating parameters associated with said mode of operation; and an input/output data channel connected to said control store for transferring data therewith which define the sequence of electrical events to be performed by said at least one mode of operation

thereby to affect treating operations particularly suited to the patient.

19. The stimulator as recited in claim 18 wherein said programmable control store defines a defibrillating mode of operation and a set of operating parameters including step wise increased energy levels for said defibrillating pulses, said executing means being responsive to said programmable control store to defibrillate the heart in accordance with the programmed mode of operation and the defined operating parameters associated therewith.

20. An implantable heart stimulator for monitoring a heart and treating a plurality of conditions of said heart, comprising:

input means for receiving various status and sensor input signals;

controller means for processing said various status and sensor input signals to determine the occurrence of a given condition from among said plurality of conditions, and for selectively performing a sequence of events defined by at least one mode of operation corresponding to and for treating said determined condition, and issuing corresponding control output signals; and

output means responsive to said control output signals of said controller means for electrically stimulating the heart so as to treat said determined condition.

21. The stimulator of claim 20 wherein said controller selectively performs a plurality of modes of operation and includes first and second processors, said first processor adapted to execute a first group of said plurality of modes of operation so as to treat a first group of a corresponding plurality of conditions, said second processor adapted to execute a second group of said plurality of modes of operation so as to treat a second group of a corresponding plurality of conditions.

22. The stimulator of claim 20, further comprising data input/output channel means for transferring data with said implantable heart stimulator.

23. The stimulator of claim 20 further including an input/output data channel for transferring data with said controller means and wherein said controller means comprises at least one programmable microprocessor for generating said output control signals in dependence on said data signals received through said input/output data channel.

24. The stimulator of claim 20, wherein said output means includes a cardiac pacer.

25. The stimulator of claim 20, wherein said output means includes a cardioverting device.

26. The stimulator of claim 20, wherein said output means comprises an automatic defibrillator.

27. The stimulator of claim 20, wherein said at least one mode of operation includes a cardiac pacer mode of operation and an automatic defibrillator mode of operation, said input means receiving a first sensor input signal corresponding to presence or absence of a naturally induced R-wave of the heart and a second sensor input signal corresponding to presence or absence of a forced R-wave of the heart, said controller means determining the absence of said natural R-wave of the heart and responding thereto by issuing a cardiac pacer control output signal to effect cardiac pacing of the heart, said controller means subsequently determining the presence or absence of said forced R-wave of the heart and responding to the absence thereof by issuing an

automatic defibrillation control output signal to effect automatic defibrillation of the heart.

28. The stimulator of claim 27, wherein said controller means responds to the presence of said forced R-wave of the heart by monitoring said R-wave sensor input signal and inhibiting further electrical stimulation of the heart until absence of said naturally induced R-wave of the heart is detected.

29. A stimulator as recited in claim 20 further including

a program control store for defining a sequence of electrical events for at least one operating mode to pace, cardiovert or defibrillate a heart; and means for further defining at least one parameter associated with said at least one operating mode.

30. A stimulator as recited in claim 29 wherein said defined parameter includes the level of intensity of a pacing signal, defibrillating pulse, or cardioverting pulse.

31. The stimulator as recited in claim 30 wherein the defined sequence of electrical events includes a set of step-wise increased energy levels for said defibrillating, and said executing means issues said defibrillating pulses in successive step-wise increased energy levels until completion of defibrillation.

32. The stimulator as recited in claim 31 wherein the defined parameter includes a preprogrammed number of defibrillating pulses.

33. The stimulator as recited in claim 30 when the defined parameter includes a preprogrammed number of defibrillating pulses.

34. The stimulator as recited in claim 30 wherein the parameters defined by said control store include any combination of the group including the number and level of pulses which treat the heart, periodicity of pulses which treat the heart, tachardia threshold rate, R-R coupling interval, ~~decrement for R-R coupling interval, width of~~

said executing means effects treatment of the heart in accordance with at least one of said defined parameters.

35. The stimulator as recited in claim 34 further comprising

an input/output data channel for transferring data with said controller means,

said control means generating said output control signals in accordance with the data signals received through said input/output data channel.

36. The stimulator as recited in claim 29 further comprising

an input/output data channel for transferring data with said control means,

said control means generating said output control signals in accordance with the data signals received through said input/output data channel.

37. The stimulator as recited in claim 20 further including a programmable control store for defining a sequence of electrical events corresponding to at least one mode of operation and associated operating parameters associated with said operation; and

an input/output data channel connected to said control store for transferring data therewith which define the sequence of electrical events to be performed by said at least one mode of operation thereby to affect treating operations particularly suited to the patient.

* * * * *

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Patent of)

ALOIS A. LANGER,)
 STEVE A. KOLENIK,)
 MARLIN S. HEILMAN,)
 MIECZYSLAW MIROWSKI and)
 MORTON M. MOWER)

Patent No.: 4,407,288
 Issued: October 4, 1983
 Assignee: Mieczyslaw Mirowski

For: IMPLANTABLE HEART STIMULATOR)
 AND STIMULATION METHOD)

**Transmittal Letter For
 Application for Patent Term Extension Under 35 USC §156 and 37 CFR §1.740**

Commissioner of Patents and Trademarks
 Box Patent Ext.
 Washington, DC 20231

RECEIVED

AUG 16 1994

Dear Sir:

**SPECIAL PROGRAMS OFFICE
 ACPATENTS**

Enclosed is an original and four photocopies of an application for patent term extension.

The application is informal under 37 CFR §1.740 insofar as written authorization for me to act on behalf of the beneficial owner, the Estate of Mieczyslaw Mirowski (now deceased), assignee of record, has not yet been received from Anna Mirowski, Personal Representative of the Estate of Mieczyslaw Mirowski.

However, the application is complete under 37 CFR §1.741, and thus please grant a filing date to the application.

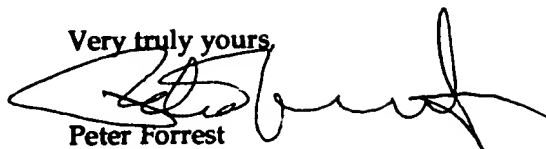
The application is being submitted by Cardiac Pacemakers, Inc., licensee of US Patent 4,407,288 and holder of the regulatory approval granted with respect to the regulatory review period creating the eligibility for extension of the term of US Patent 4,407,288. I am authorized to act on behalf of Cardiac Pacemakers, Inc. in this regard.

To the extent that this situation is contrary to 37 CFR §1.34(a), please grant a limited and temporary suspension of 37 CFR 1.34(a), *sua sponte* and without petition, pending resolution of the matter in response to an order to show cause or by way of petition, as set forth in 37 CFR §1.740(c).

Please charge the \$1,000 fee for the application for patent term extension under 37 CFR §1.20(j), along with any underpayment, or credit any overpayment, to Deposit Account 03-0667.

If you have any questions, please contact me at your convenience.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Peter Forrest', written over the typed name.

Peter Forrest

Registration Number 33,235

Assistant Secretary of Cardiac Pacemakers, Inc.

August 15, 1994

CARDIAC PACEMAKERS, INC.

Mail Stop A390

4100 Hamline Avenue North

St. Paul, MN 55112-5798 USA

1-800-CARDIAC, ext. 4400 (voice)

(612) 582-4400 (direct voice)

(612) 582-2926 (facsimile)